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TECHNICAL PRODUCT RISK ASSESSMENT: STANDARDS, INTEGRATION IN THE ERM MODEL AND UNCERTAINTY MODELING

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Abstract: *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 development. This is achieved by quantifying risk levels with the aim of determining the scope of the required safety measures and systems. The theory of probability is used as a tool for modeling uncertainties in the assessment of that risk. In the last forty years are developed new mathematical theories have proven to be better at modeling uncertainty when we have not enough data about uncertainty events which is usually the case in product development. Bayesian networks based on modeling of subjective probability and Evidence networks based on Dempster-Shafer theory of belief functions proved to be an excellent tool for modeling uncertainty when we do not have enough information about all events aspect.*

Keywords: *technical product, risk assessment, risk standards, ERM, uncertainty modeling*

1. Introduction

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.

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.

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Technical product as the machine tool shown on Figure 1. have to be safe for use and the best way to realize this requirement is by creating and realizing the “inherently safe design structures” (Blue Guide, 2011) which is achieved by the process of designing, by adequate manufacturing processes involving all testing and controls, and by adequate work processes in used area.

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 (Djapic *et al.*, 2013; Mihai *et al.*, 2015).

Figure 1. Machining center Balestrini CMS, portal type with multi-axis CNC for woodworking

Far beyond to be limited to the woodworking, this action of regulation involves different industrial sectors and products with the unique scope to assure a total safety. As a consequence, a very large number of standards has been developed and progressively implemented. Some of them will be presented and discussed inside this article. At the same time, several investigations propose interesting arguments for reflection respect to the possibility to overtake these standards in specific situations, with the aim at offering even safer conditions (in product design or processing). For instance, in Fragassa (2015), the real limits emerging in the application of traditional ISO while dealing with innovative ceramic solutions is detailed. Another evidence of the large complication of a practical application of safety standards is available in Pavlovic and Fragassa, (2015), where a general overview about the norms and regulations existing for quadricycles and microcars is reported, as part of an extremely large and complex discussion that spread all over the World involving Governments, Organizations, Manufactures and citizens.

Coming back to the woodworking, the same authors also realized an interesting experience of misalignment between current standards and modern needs in design of machine tools (Pavlovic and Fragassa, 2016). In particular, the paper deals with the optimization of flexible barriers used as safety protection in woodworking when significantly different respect to the most common ones. In is evident how standards manage to get through the technology advances with difficulty.

In all 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. A similar approach, is also proposed by Fragassa *et al.* (2014) referring to a practical application to the automotive industry, where significant improvements in the reliability of large mass products were obtained thanks to the risk assessment, implemented in accordance with a Total Quality (TQ) strategy.

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.

Estimates of risk are becoming central to decisions about many engineering systems. In many important cases we do not have enough data on the events we try to design for. In this way, modeling and measurement uncertainty becomes central to the risk assessment of a technical system.

Probability is the most suitable method for modeling random uncertainty when there is sufficient information on the probability distribution. But very rarely we have enough information to make the reliability could use the classical theory of probability to model uncertainty. Therefore, for modeling uncertainties we use other mathematical structures and tools that were developed last thirty years such as Evidence nets (developed on the base of Dempster-Shafer theory (Djapic, 2005) and Bayesian nets based on subjective belief (probability).

This paper present concept of integration risk assessment in the technical product development process, the concept of international standardization in the risk management field and on the end base information about Evidence and Bayesian nets and is possibility use in technical product risk assessment.

2. Concept of standardization in the risk management field

Experience in the 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.

Presenting the standards 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 (ISO) and some of the most significant national standardization bodies (Table 1).

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 2. 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 2 depicts complete hierarchy structure of international and regional standards in the field of risk management, which are of importance for implementing the New Approach Directive (NAD).

At the highest generic level, there is the standard ISO 31000:2009 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 and ISO/IEC Guide 51:1999 standards.

This group of standards defining the terms might also be extended by standard ISO 12100:2010, 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. The requirements for technical products safety 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 development related to safety of the products.

In the course of product development, 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.

Table 1. The most influential international and national risk management standards

Publisher	Standards	Publisher	Standards
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/IEC 31010:2009, ***Risk management -- Risk assessment techniques***	BSI (Great Britain)	**BS 25999-2:2007**, *Business continuity management. Specification*
ISO	**ISO 12100:2010,** *Safety of machinery -- General principles for design -- Risk assessment and risk reduction*		**BS 31100:2011**, *Risk management. Code of practice and guidance for the implementation of BS ISO 31000*
	Former ISO 14121:2007, ***Safety of machinery -- Risk assessment -- Part 1 and Part2***		**BS 6079-3:2000**, *Project management. Guide to the management of business related project risk*
	ISO 14971:2007, *Medical devices -- Application of risk management to medical devices*	ON (Austria)	**ONR 49000:2010**, *Risk Management for Organizations and Systems - Terms and basics - Implementation of ISO 31000*
ISO/IEC	**ISO/IEC 27005:2011**, ***Information technology -- Security techniques -- Information security risk management***		**ONR 49001:2010**, *Risk Management for Organizations and Systems - Risk Management - Implementation of ISO 31000*
ISO	**ISO 14798:2009**, *Lifts (elevators), escalators and moving walks -- Risk assessment and reduction methodology*		**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*
	ISO 17776:2000, *Petroleum and natural gas industries -- Offshore production installations -- Guidelines on tools and techniques for hazard identification and risk assessment*		**ONR 49002-2:2010**, *Risk Management for Organizations and Systems - Part 2: Guideline for methodologies in risk assessment - Implementation of ISO 31000*
EN	**EN 1127-1:2011,** *Explosive atmospheres. Explosion prevention and protection. Basic concepts and methodology*		**ONR 49002-3:2010**, *Risk Management for Organizations and Systems - Part 3: Guidelines for emergency, crisis and business continuity management - Implementation of ISO 31000*
	EN 13463-1:2009, *Non-electrical equipment for use in potentially explosive atmospheres. Basic method and requirements*		**ONR 49003:2010**, *Risk Management for Organizations and Systems - Requirements for the qualification of the Risk Manager - Implementation of ISO 31000*

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: (1) identification of hazards; (2) risk assessment due to these dangers, and (3) assessment of acceptability of the selected safety measures.

Thus, a set of generic standards ensued for assessing risks in the NAD, such as: ISO 12100:2010, former ISO 14121-1:2007 for machines products, EN ISO 14971: 2002 for medical products, ISO TR 14798:2006 for lifts, 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 3, 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 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 12100:2010, 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 (Figure 2).

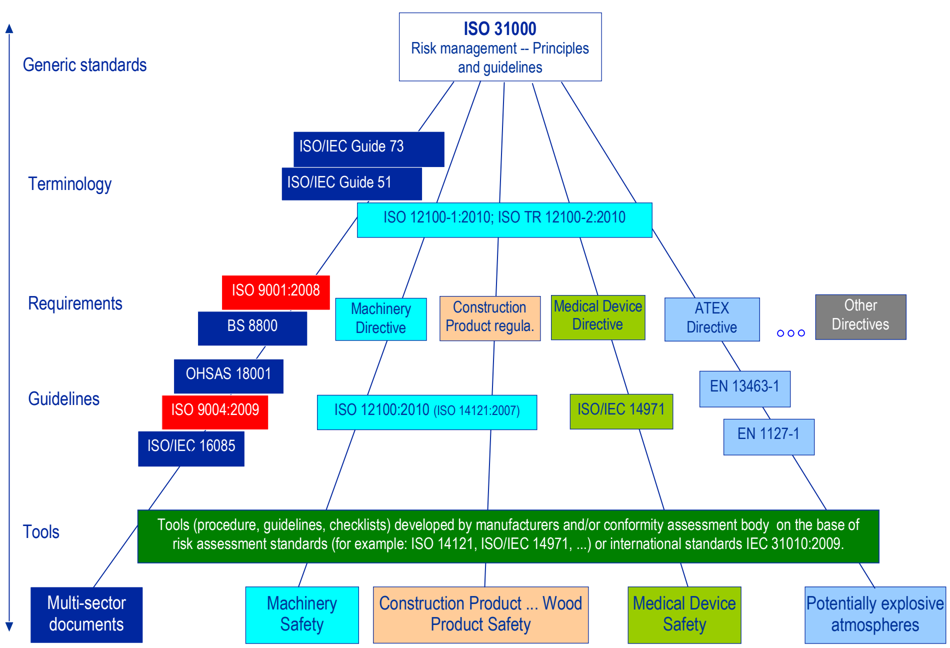


Figure 2. Hierarchy structure of standards in the risk management field, of importance in implementing the EU technical legislation (Djapic, 2013) on the base of CEN/BT WG 160)

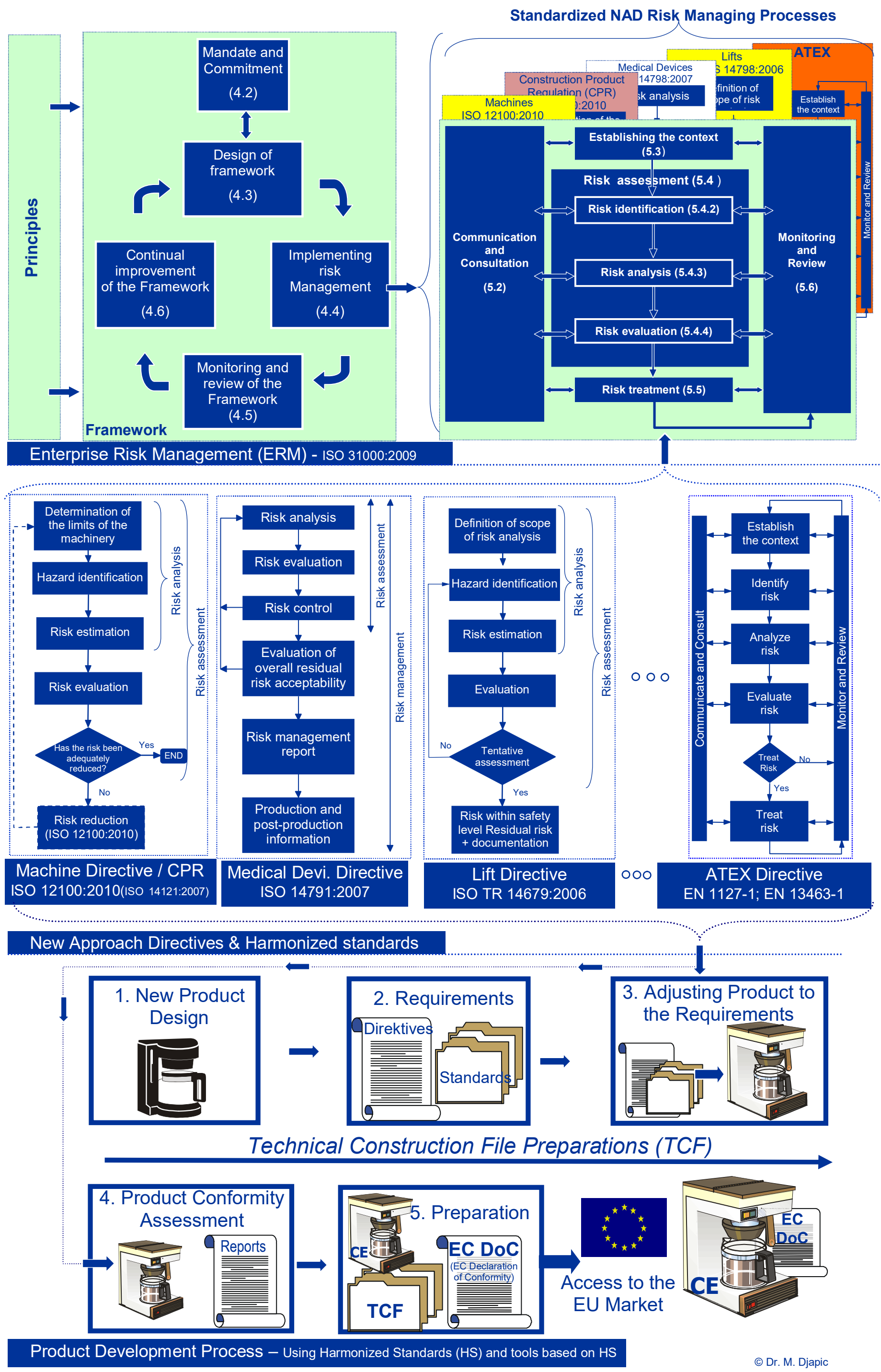


Figure 3. Integrating risk assessment in NAD into the ERM model, according to standard ISO 31000:2009 (Djapic, 2013)

2.1. Definition of Risk in the international standards

Significant efforts in the risk defining were exerted by the international organizations for standards (ISO 31000, ISO/IEC Guide 73, ISO 12100) as well as by some national ones, first and foremost the Australia & New Zealand standardization organizations (AS/NZS 4360:2004).

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 is serves for. It is still topical as it can be found in many standards such as the standards serving as guidelines for conducting the risk analysis and assessment in the EU New Approach directives, such as, for instance, former ISO 14121:2007 standard.

Standard ISO 31000:2009 on risk management and ISO/IEC 73:2009 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 (Aven, 2009; Aven, 2010).

Out of these definitions, the conclusions that follow can be drawn (Aven, 2009):

- 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 IEC 31010 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 (evidence networks), developed on the basis of the *Dempster–Shafer* theory of belief function. Also it is important to mention that the *IEC-International Electro-technical Commission* has developed standard related to the techniques that can be used in risk management. This is the standard IEC 31010:2009, 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.

3. Technical product risk assessment integration into the enterprise risk management (ERM) model

3.1. The Concept of the Enterprise Risk Management

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 ingoing events, 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 (Erben, 2008): Total Risk Management (TRM), Integrated Risk Management (IMR), Holistic Risk Management or 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.

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 national standardization body for example DIN, BS, etc.), 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 (ARMIC, 2010), 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) (ARMIC, 2010).

Thus, as stated by Erben in (Erben, 2008), 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)

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 (Knight, 2007), 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 is 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.

3.2. Risk Assessment in New Approach

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 in the New Approach Directives into the ERM structure is given in Fig. 3.

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 12100:2010, former 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 Fig. 3. 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).
- At the operational level, in the course of product conformity assessment, as shown in Figure 2 and Figure 3, 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 14798:2007, 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 2.

3.3. Risk Assessment Integration in to the Product Development Process

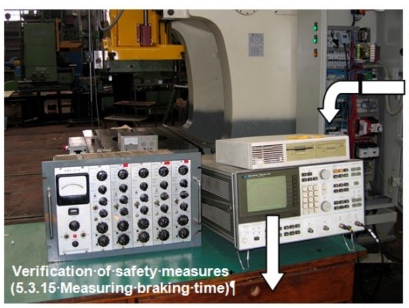
The designing process is a set of activities and its related resources, through which team of designers develops or selects means for achieving a certain goal under strictly defined conditions and restrictions.

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 product All designers and employees who take decisions in product development process have to be familiar with the general and/or specific processes for risks assessment as defined in the relevant ISO or EN standards.

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 12100:2010, 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, 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.

Risk assessment in that process is the constituent part of the phase in which the designer adjusting its design to the requirements (create design solution) and on the other hand the constituent part of final product conformity assessment (final control and inspection) (Figure 3) conducted by the organization itself and/or the body for conformity assessment.



Safety measures verification (EN 692:1996)

Subclasses	Safety requirements and/or measures	Visual inspection (see note 1)	Performance check/test (see note 2)	Measurement (see note 3)	Drawings/ Calculations (see note 4)
5.3.14	Two-hand control devices	x	x	x	x
5.3.15	Safety distance	x	x	x	x
5.3.16	Motor and clutch interlocking	x	x		x
5.3.17	Single stroke device	x	x		x
5.8	**PROTECTION AGAINNST OTHER HAZARDS**				
5.8.1	ELECTRICAL HAZARDS	x		x	x
5.8.2	THERMAL HAZARDS	x		x	x
5.8.3	HIGH PRESSURE FLUID EJECTION HAZARDS	x	x		
5.8.4	HAZARDS GENERATED BY NOISE			x	
5.8.5	HAZARDS GENERATED BY VIBRATION	x	x	x	
5.8.7	HAZARDS GENERATED BY NEGLECTING ERGONOMIC PRINCIPLES	x	x	x	x

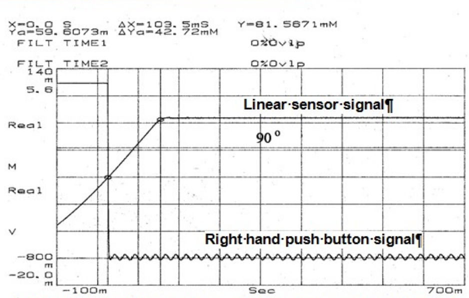


Figure 4. Conformity assessment of mechanical press ARP 160 - Verification of safety measures (Djapic, 2008)

3.4. Example: Risk Assessment Integration into the Mechanical Presses Conformity Assessment

All designers and employees who take decisions in product development process have to be familiar with the general and/or specific processes for risks assessment which is required by NAD (Figure 3). Risk assessment in that process is the constituent part of the phase in which the designer adjusting its design to the requirements (create design solution) and on the other hand the constituent part of final product conformity assessment (final control and inspection) (Figure 4) conducted by the organization itself and/or the body for conformity assessment.

To illustrate product conformity assessment on the Figure 4 is display some of the results and verifications performed on the mechanical presses ARP 160 (Djapic, Zalikovic *et al*., 2008).

4. Uncertainty modeling in the risk assessment

Standard ISO 31000:2009 on risk management and ISO/IEC 73:2009 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.

Type of Information	Models
Imprecision Information	Theory of fuzzy sets Theory of possibilities
Uncertainty Information	Theory of probabilities Theory of belief functions (**Dempster-Shafer evidence theory**)

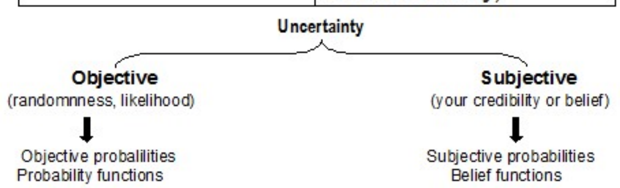


Figure 5. Modeling uncertainty (Adapted by Djapic, 2008)

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.

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

- 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 /Aven in 16/ 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 (Djapic, 2005). 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.

If we analyze the literature on types of uncertainty, we can conclude the following. There are two types of uncertainty:

- **Aleatory (irreducible) uncertainty** refers to the inherent randomness or unpredictability of the system
  - Modeling by - probability theory.
- **Epistemic (reducible) uncertainty** - from lack of knowledge and such, is sometimes called imprecision or subjective uncertainty
  - Modeling by – Dempster-Shafer evidence theory or
  - Modeling by probability theory (subjective measure)

Finally comments on modeling uncertainty in risk assessment:

- There is a rich collection of theories for modeling all types of uncertainty
- These theories are not in conflict with Bayesian or classical probability but rather provide tools that complement probabilistic methods for risk assessment
- Probability is the most suitable method for modeling random uncertainty when there is sufficient information on the probability distribution
- Non-probabilistic methods (evidence theory, subjective probability) can be useful in modeling reducible uncertainty

4.1. Base of Dempster-Shafer belief function theory

Making conclusions (reasoning) about certain situation from the real world is often in difficult circumstances with insufficient knowledge, no clearly defined criteria and mutual antagonism. Information about evidence can come from different resources: based on a person's experience, from signals recorded by appropriate sensors, from the contents (the context) of published papers and so on. Such evidence are rarely clearly delimited; it's often incomplete, ambiguous in its meaning and full of flaws.

Dempster-Shafer belief function theory provides powerful tools for mathematical presentation of the subjective (opposite of what probability theory is based on) uncertainty while it relies mainly on possibility of explicit definition of ignorance (Djapic, 2008). It, actually, represents the generalization of Bayesian theory of conditional probability.

The model of belief function consists of variables, possible values of these variables and the evidence that support the variables. Variables are individual questions about any aspect of the problem under consideration. Answers on posed questions can be made based on data gathered from different sources, or from the context of published papers, from data acquired on measured values, from expert's opinion etc. Fully unified support for possible answer is called a evidence. Evidence can be described by belief functions that are defined as follows.

Definition.1. (Djapic, 2008) Let Θ be a finite nonempty set called the frame of discernment, or simply the frame. Mapping Bel: 2Θ→[0,1] is called the (unnormalized) belief function if and only if a basic belief assignment (bba) m: 2Θ→[0,1] exists, such that:

$$\sum_{A \subset \Theta} m(A) = 1 \quad (1)$$

$$Bel(A) = \sum_{B \subset A, B \neq \varnothing} m(B) \quad (2)$$

$$Bel(\varnothing) = 0 \quad (3)$$

Value m(A) can be taken as a measure of one's belief that is committed exactly for subset A and it's moving freely within it.

Condition (1) shows that one's entire belief that is supported by the evidence may have a maximum value of one and the condition (3) refers to the fact that one's belief that was committed to an empty set must be zero.

Value Bel(A) represents the total belief that is committed to set A and all its subsets.

Each subset of A whose m(A)>0 is called focal element.

The empty belief function is a function with m(Θ)=1 and m(A)=0 for all subsets of A≠Θ. This function represents complete ignorance about the problem under consideration.

4.2. What are the Evidential Systems (Nets)?

Valuation Based Systems - VBS is an abstract framework proposed by Shenoy /3/ for representing and reasoning on the basis of uncertainty. It allows representation of uncertain knowledge in various domains, including Bayes' probability theory, Dempster-Shafer's theory of evidence which is based on belief functions and Zadeh-Dubais-Prad theory of possibility. Graphically presented VBS is called valuation network /4/.

VBS consists of set of variables and set of valuations that are defined on the subsets of these variables. Set of all variables is denoted by U and represents a space covered with problem which is under consideration. Each variable represents a relevant aspect of a problem. For each variable Xi will be used ΘXi to denote the set of possible values of variables called the frame of Xi. For a subset A (|A|>1) of U, set of valuations that are defined over ΘA represents the relationship between variables in A. Frame ΘA is a direct (Cortesian) product of all ΘXi for Xi in A. The elements ΘA are called configurations of A.

Knowledge presented in this type of valuations is called generic or general knowledge (Figure 6), which can be represented as a knowledge base in expert systems.

The VBS also defines valuations on individual variables, which represents so-called factual knowledge, and it constitutes database in expert systems (Figure 6). For a problem, general-generic knowledge defines an expert. During reasoning process that knowledge won't be modified. Factual knowledge will vary in accordance with condition of a problem currently being under consideration. The VBS treats on the same way these two kinds of knowledge.

The VBS systems suited for processing uncertain knowledge described by functions of belief function theory are called Evidential Reasoning Systems or Evidential Systems, and valuation networks are now called evidential networks (EN) (Figure 6, 7 and 8).

The objective of reasoning based on the evidence is an assessment of a hypothesis, in case when the actual evidence are given (the facts).

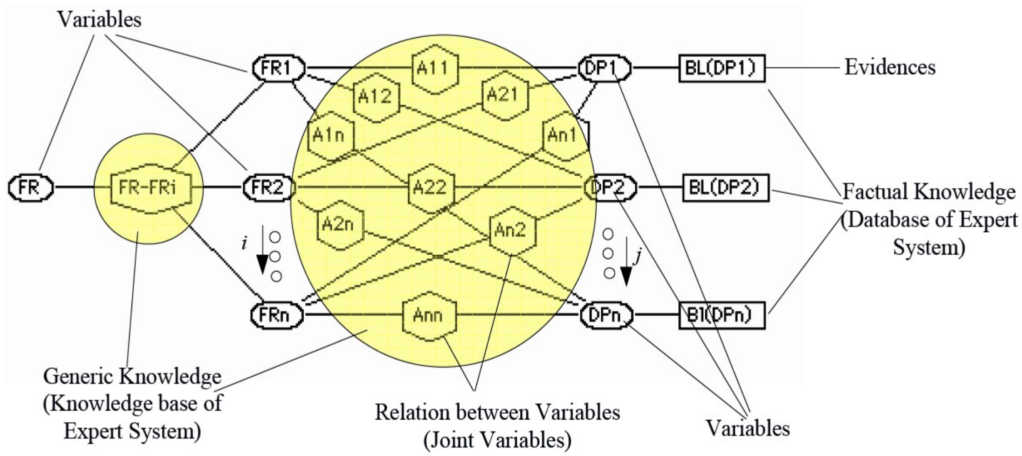


Figure 6. The concept of evidential networks

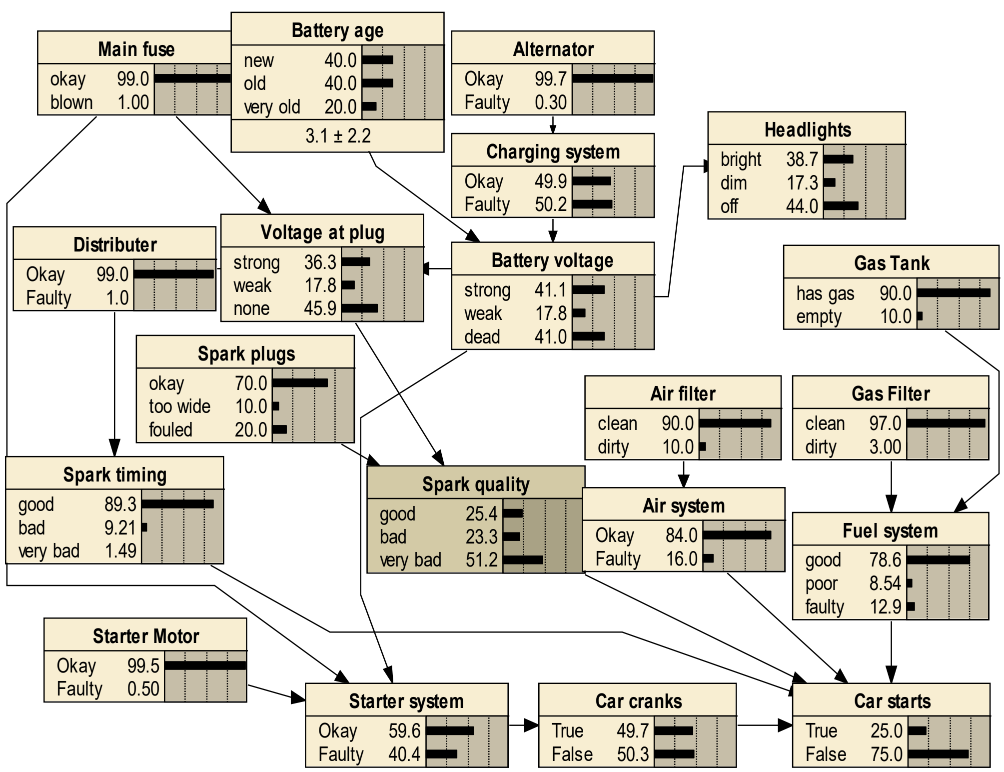


Figure 7. Example of the Bayesian nets (Test example from Notica software)

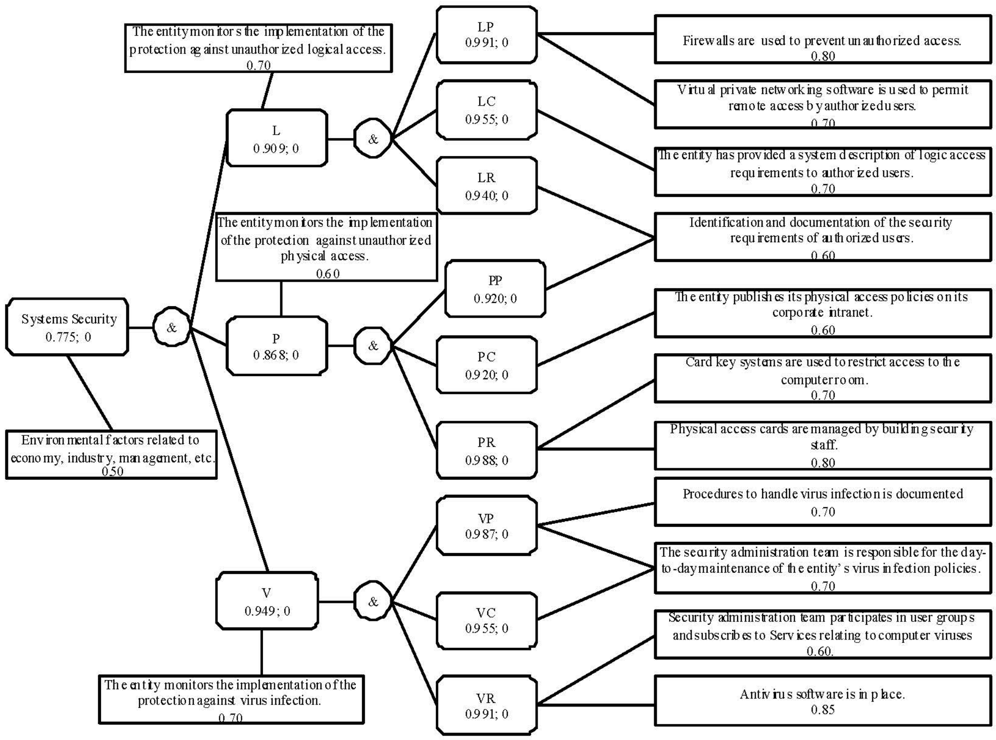


Figure 8. Example Evidential nets (Srivastava and Shafer, 1992)

5. Conclusions

European Union has accomplished, through introducing New Approach a breakthrough in the field of technical product safety. This is achieved by quantifying risk levels, in the course of the designing process. 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. Risk assessment explicitly takes account of: (1) uncertainty, (2) the nature of that uncertainty, and (3) how it can be addressed.

There is a rich collection of theories for modeling all types of uncertainty.

Probability is the most suitable method for modeling random uncertainty when there is enough information

Non-probabilistic methods (evidence Dempster-Shafer theory, Bayesian subjective probability) can be useful in modeling reducible uncertainty when there is not enough information which is prevalent.

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References:

AIRMIC (2010), Alarm, IRIM, A structured approach to Enterprise Risk Management (ERM) and the requirements of ISO 31000, The Public Risk Management Association, London, UK.

Aven, T. (2009). Perspectives on risk in a decision-making context – Review and discussion. *Safety Science*, *47*(6), 798-806. http://dx.doi.org/10.1016/j.ssci.2008.10.008

Aven, T. (2010). 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*. 1, 7-14.

Blue Guide: Guide to the Implementation of Directives Based on the New Approach and Global Approach, by the European Commission, (November 2011). Retrieved from: http://ec.europa.eu/ enterprise/

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

Djapic, M. (2005). *Evidential Systems in Product and Process Development*, Intelligent Manufacturing Series of Monographs, 9, LOLA Institute, Belgrade.

Djapic, M., Lukic, Lj., & Popovic, P. (2013). Technical product risk assessment integration into the enterprise risk management, *Technical Gazette*, *20*(4), 721-730.

Djapic, M., Zeljkovic, V., & Vojinovic, M. (2008). Machine Tools Harmonization with EU Technical Legalizations Requirements, *International Journal for Quality research*, *2*(3), 171-177.

Erben, E.B. (2008). *Risk Management Standards – role, benefits & applicability*, 2nd European Risk Conference, Università Bocconi, September 11-12.

Fragassa, C. (2015). Limits in Application of International Standards to Innovative Ceramic Solutions. *International Journal for Quality Research*, *9*(2), 279-298.

Fragassa, C., Pavlovic, A., & Massimo, S. (2014). Using a Total Quality Strategy in a new Practical Approach for Improving the Product Reliability in Automotive Industry, *International Journal for Quality Research*, *8*(3), 297–310.

IEC 31010:2009, Risk management — Risk assessment techniques, International Electrotechnical Commission.

ISO 12100:2010 Safety of machinery — General principles for design -- Risk assessment and risk reduction, International Organization for Standardization.

ISO 14121-1:2007 Safety of machinery — Risk assessment — Part 1:Principles, International Organization for Standardization.

ISO 14971:2007 Medical devices — Application of risk management to medical devices, International Organization for Standardization.

ISO 31000:2009 Risk management -- Principles and guidelines, International Organization for Standardization.

ISO EN 1127-1 2007 Explosive atmospheres - explosive prevention and protection basic concepts and methodology, International Organization for Standardization.

ISO TR 14798:2006 Lifts (elevators), escalators and moving walks -- Risk assessment and reduction methodology, International Organization for Standardization, www.iso.org

ISO/IEC Guide 51:1999 Safety aspects - Guidelines for their inclusion in standards. International Organization for Standardization.

ISO/IEC Guide 73 Risk Management - Vocabulary - Guidelines for use in standards, International Organization for Standardization.

Knight, K., (2007). *Future ISO 31000 standard on risk management*, ISO Management Systems, July-August, 8-11.

Lukic, Lj. (2015). *Automatic Machine with CNC Control and Technologies with Multiple – Axes Wood Processing in Small and Medium Enterprises - MAMWOOD*, Technical Report WP-6, International Adriatic IPA Project AdriaHUB.

Mihai, O., Vlad, M., & Radu, V. (2015).Technical Analysis of MOOCs. *TEM Journal*, *4*(1), 60-72.

Pavlovic, A., & Fragassa, C. (2015). General considerations on regulations and safety requirements for quadricycles. *International Journal for Quality Research*, *9*(4), 657–674.

Pavlovic, A., & Fragassa, C. (2016) Analysis of flexible barriers used as safety protection in woodworking. *International Journal of Quality Research*, *10*(1), 71-88.

Savoia, M., Stefanovic, M., & Fragassa, C. (2016). Merging Technical Competences and Human Resources with the Aim at Contributing to Transform the Adriatic Area in Stable Hub for a Sustainable Technological Development. *International Journal of Quality Research*, *10*(1), 1-16.

Srivastava, R.P., & Shafer. G. (1992). Belief-Function formulas for audit risk. *The Accounting Review*, *67*(2), 249-283.

Standards Australia & Standards New Zealand Committee OB/7 on Risk Management (2004). Risk management, AS/NZS 4360:2004.

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