June 22, 2011 (Wednesday) 55th EOQ Congress

CONCURRENT SESSIONS **Wednesday 8:30 – 12:30**
KEMPINSKI HOTEL CORVINUS **Erzsébet tér 7-8, Budapest V.**

REGINA BALLROOM III. **Wednesday 8:30 – 10:30**

21.1. FUTURE OF QUALITY AND RISK MANAGEMENT

Session Chair: ***Gregory H. Watson,*** *Acting Chairman and President of the International Academy for Quality, Finland*

9.25 ISO 9004 and Risk Management – New Approaches of Sustainable Development
Liliana Nitu, Romanian Association for Quality, Romania

Nitu, Liliana (Romania)

Beginning from May 2005 up to now she has been working in the Romanian Association for Quality (ARC) being the National Representative of Romania at the European Organization for Quality (EOQ). Now she is Secretary General, Member of the Board, EOQ Representative. Earlier she worked at the Research Institute for Informatics (ICI), Quality Assurance Compartment as Analyst and Scientific Researcher. Now she makes Doctoral Studies as Candidate of PhD Degree at the Polytehnical University, Bucharest, Romania.
She published over 25 papers in Romanian and international magazines on quality topics and attended at EOQ Congresses as speaker.

ISO 9004 and Risk Management – New Approaches of Sustainable Development

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Abstract:

The action to implement sustainable development measures is, during the last decade, a key point of discussion, at the international and national level, leading, in recent years, to more and more tangible gains. In this context, the new edition of international standard ISO 9004:2009 - "Managing for the sustained success of an organization – A quality management approach" brings quality management system to a new stage of achieving and maintaining business objectives in the long-term. The standard provides a model for a more holistic approach and for identifying the system's maturity levels, which can be used as a basis for benchmarking and improvement identification.

*In our ever-changing, competitive and dynamic world, the sustained success of an organization is the result of keeping balance between the complex and demanding business environment challenges and the expectations of interested parties, assuring the "**Triple Bottom Line: environment, society, economy"**.*

ISO 9004:2009 adds some new elements to the general framework, emphasizing in particular:

- *the ethical-social perspective;*
- *the organization mission and vision;*
- *the ability to turn strategies into actions and correlate the results to the objectives.*
- *the risk management;*
- *the adaptability and flexibility, the organization's ability to change in response to changing conditions of risk and opportunity;*
- *the knowledge management;*
- *the alignment and linking with other management systems*

In this context, Risk Management become a key starting point for management systems implementation for an organization which is interested in continual improvement of its overall performance, efficiency and effectiveness, and publication of ISO 31000 is an evidence of understanding the need for widespread use of this concept in conjunction with all types of management systems.

Starting from a previous designed model of an integrated management system based on the risk management and taking in account the model provided by ISO 9004, the paper will present practical aspects of implementing ISO 9004 and risk management processes into an organization. The result of risks aggregation will be used to provide information to support decisions that influence the achievement of the organization's objectives.

In the end of the paper, it will be presented some results of applying of self-assessment tool, enabling organization to:

- *establish and benchmark the level of maturity, covering leadership, strategy, resources, processes, monitoring and measurement, improvement, innovation and learning*
- *identify their strengths and weaknesses*
- *identify opportunities for either improvements or innovation, or both.*

1. Introduction

The action to implement sustainable development measures is, during the last decade, a key point of discussion, at the international and national level, leading, in recent years, to more and more tangible gains. In our ever-changing, competitive and dynamic world, the sustained success of an organization is the result of keeping balance between the complex and demanding business environment challenges and the expectations of interested parties, assuring the "**Triple Bottom Line: environment, society, economy"**.

In this context, the new edition of international standard ISO 9004:2009 - “Managing for the sustained success of an organization – A quality management approach” brings quality management system to a new stage of achieving and maintaining business objectives in the long-term. The standard provides a model for a more holistic approach and for identifying the system’s maturity levels, which can be used as a basis for benchmarking and improvement identification.

ISO 9004:2009 [1] adds some new elements to the general framework, emphasizing in particular:

- the ethical-social perspective;
- the organization mission and vision;
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- the risk management;
- the adaptability and flexibility, the organization’s ability to change in response to changing conditions of risk and opportunity;
- the knowledge management;
- the alignment and linking with other management systems

Obviously, Risk Management become a key starting point for management systems implementation for an organization which is interested in continual improvement of its overall performance, efficiency and effectiveness, and publication of ISO 31000 [2] is an evidence of understanding the need for widespread use of this concept in conjunction with all types of management systems. Therefore, a model designed special to help organizations to integrate the requirements of different management systems and risk management, in the same time, will be very useful in the global context of sustainable development.

2. Connection between ISO 9004 process approach model and the model for integrated management system based on risk management

The process approach model presented in ISO 9004: 2009 (figure 1) includes all issues covered by the ISO 9001 model, but also includes some additional elements like as: needs and expectation of interested parties, strategy, innovation and learning etc. This new elements bring the ISO 9004 model closer to the designed model based on risk management [3] through some common issues added to the ISO 9001 by both, ISO 9004 and the designed model for integrated management system based on risk management (figure 2).

If we are talking about sustainability concept, we talk about the three dimensions of needs that are defining the concept:

- Social well-being and equity for both employees and affected communities
- Economic prosperity and continuity for the business and all interested parties
- Environmental protection and resource conservation, both local and global

As expected, ISO 9004:2009 model as well as the other standards of ISO 9000, refers mainly to the economic dimension of the concept, and to ensure the balance between all of them we still need the ISO 14000 series of standards for environmental protection and OHSAS, SA8000 / ISO 26000 for the social dimension. Because of including the needs and expectation of interested parties into the process approach model, for those organizations, which already implemented ISO 9001, the implementation of ISO 9004:2009 could be a useful step towards sustainable development.

In the proposed model for integrated management system based on risk management the focus is on risk management process, but the target is the same: achievement of needs and expectation of all interested parties. Anyway, the risk management concept, even if is not expressly stated in the ISO 9004 process approach model, is still mentioned inside of the text of the standard, but for the practical aspects related to application, the standard refers to the ISO 31000.

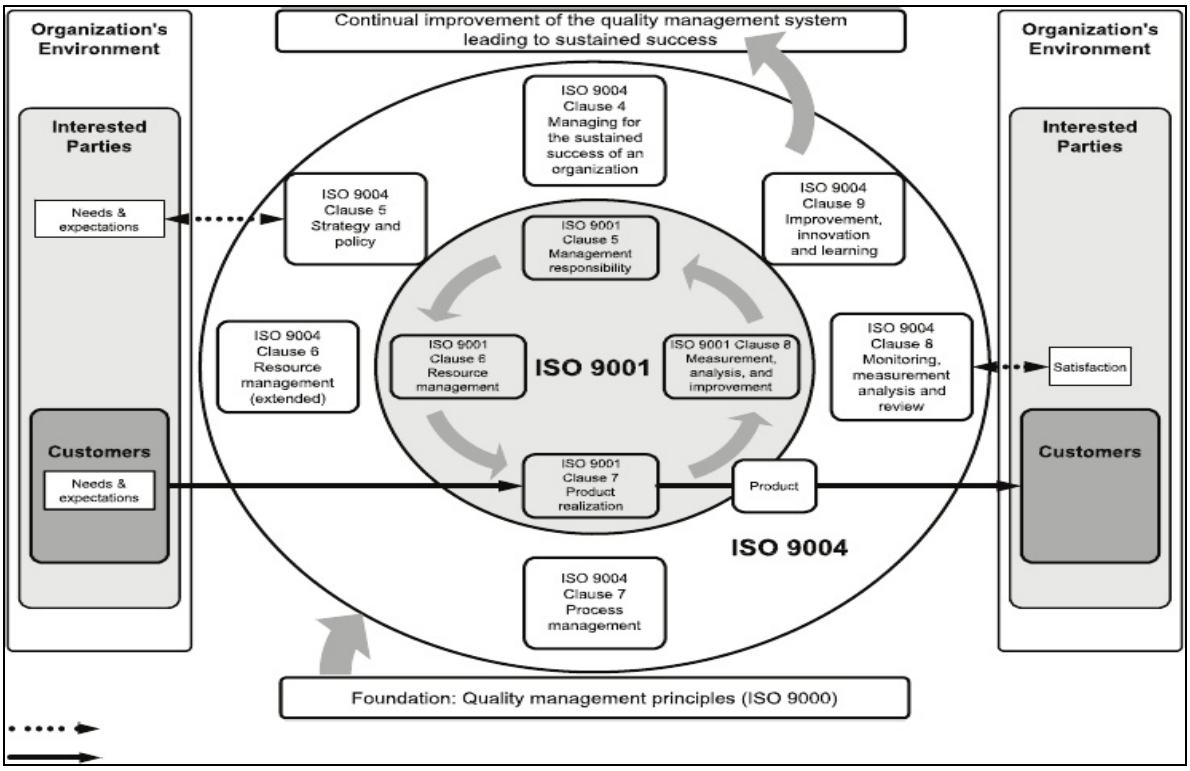


Fig. 1. Process Approach Model (ISO 9004: 2009)

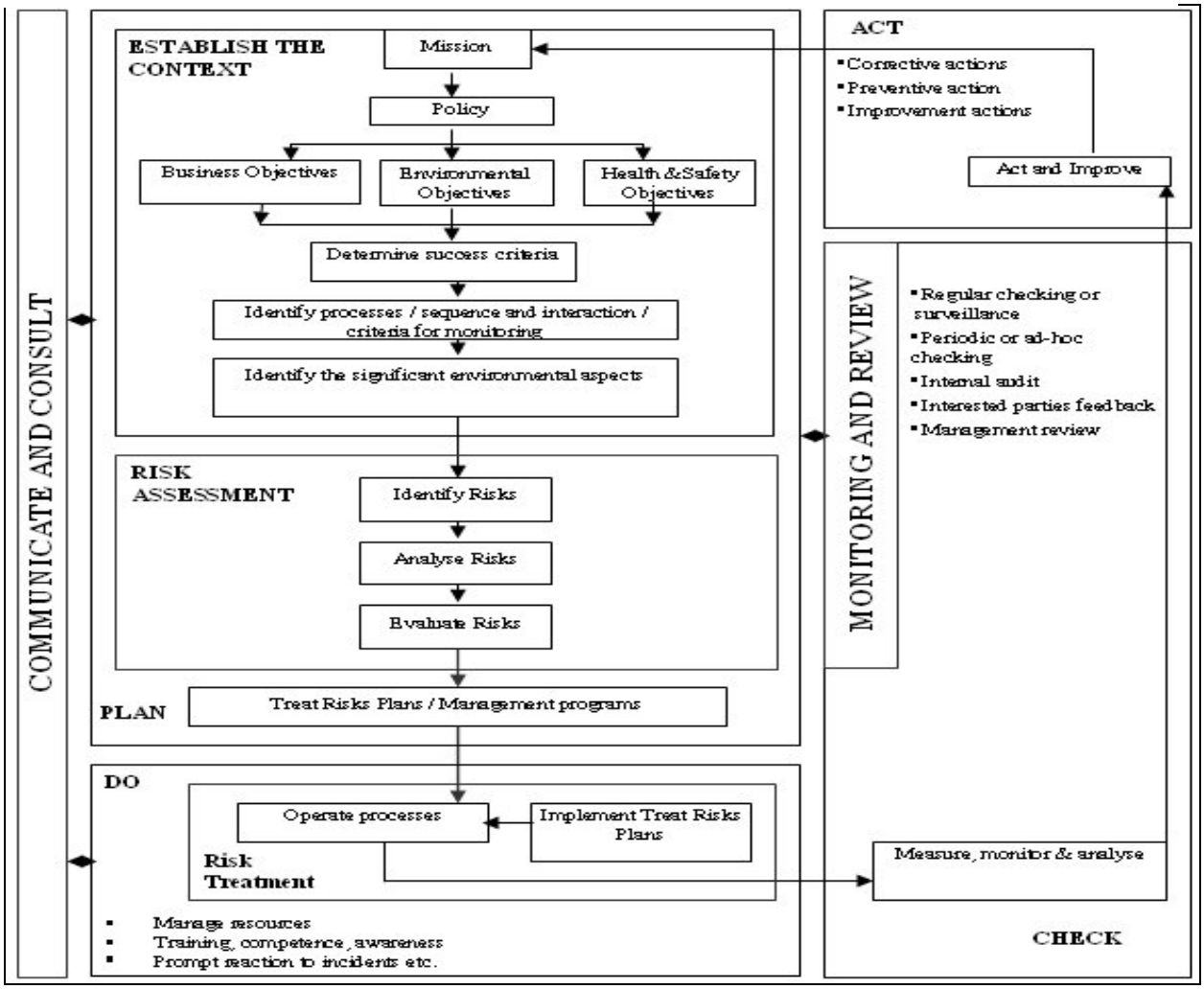


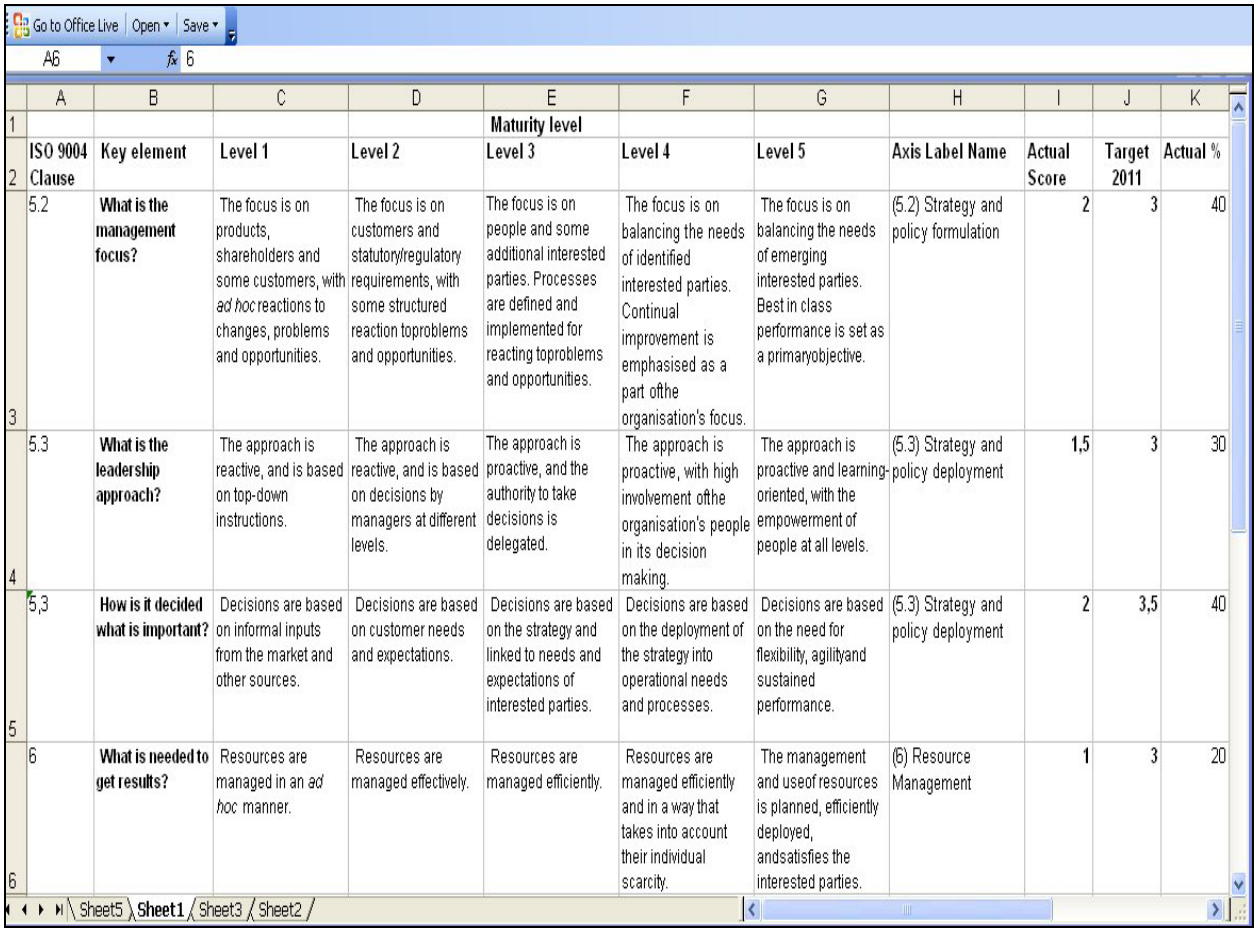
Fig. 2. Model for Integrated Management System based on risk management

3. Practical aspects of implementing ISO 9004 and Risk Management

Both models, previously presented, are following the PLAN – DO – CHECK – ACT Cycle, so are compatible each other, making possible to use them simultaneously. The methodology used to implement ISO 9004 and risk management are briefly presented below, referring the results obtained into an industrial company.

In the first stage of implementation, a company should identify the activities of the company, the location and all interested parties, including regulators or groups living in the region. Related to these interested parties, the company will update the mission, the strategy and the objectives. A strategic level self-assessment, will enable the organization to establish the current level of maturity and the target for next period, and to identify strengths and weaknesses, opportunities for improvements or innovation and to develop a management plan for the short or / and medium term horizon.

To determine the current maturity level was developed an Excel workbook which allows quick calculation and plotting graphs necessary to interpret the results. The results of such a self-assessment in a specific company are presented in figure 3.



	A	B	C	D	E	F	G	H	I	J	K
1					Maturity level						
2	ISO 9004 Clause	Key element	Level 1	Level 2	Level 3	Level 4	Level 5	Axis Label Name	Actual Score	Target 2011	Actual %
3	5.2	What is the management focus?	The focus is on products, shareholders and some customers, with *ad hoc* reactions to changes, problems and opportunities.	The focus is on customers and statutory/regulatory requirements, with some structured reaction toproblems and opportunities.	The focus is on people and some additional interested parties. Processes are defined and implemented for reacting toproblems and opportunities.	The focus is on balancing the needs of identified interested parties. Continual improvement is emphasised as a part ofthe organisation's focus.	The focus is on balancing the needs of emerging interested parties. Best in class performance is set as a primaryobjective.	(5.2) Strategy and policy formulation	2	3	40
4	5.3	What is the leadership approach?	The approach is reactive, and is based on top-down instructions.	The approach is reactive, and is based on decisions by managers at different levels.	The approach is proactive, and the authority to take decisions is delegated.	The approach is proactive, with high involvement ofthe organisation's people in its decision making.	The approach is proactive and learning-oriented, with the empowerment of people at all levels.	(5.3) Strategy and policy deployment	1,5	3	30
5	5,3	How is it decided what is important?	Decisions are based on informal inputs from the market and other sources.	Decisions are based on customer needs and expectations.	Decisions are based on the strategy and linked to needs and expectations of interested parties.	Decisions are based on the deployment of the strategy into operational needs and processes.	Decisions are based on the need for flexibility, agilityand sustained performance.	(5.3) Strategy and policy deployment	2	3,5	40
6	6	What is needed to get results?	Resources are managed in an *ad hoc* manner.	Resources are managed effectively.	Resources are managed efficiently.	Resources are managed efficiently and in a way that takes into account their individual scarcity.	The management and useof resources is planned, efficiently deployed, andsatisfies the interested parties.	(6) Resource Management	1	3	20

Fig. 3. Results of strategic self-assessment

On a graphic, the results can be shown in figure 4.

From this first self-assessment result, it can be seen that the weakness points of that company are:

- Resource Management
- Strategy and policy deployment and
- Improvement, innovation and learning,

while the strengths it seems to be, at this moment, the Process Management.

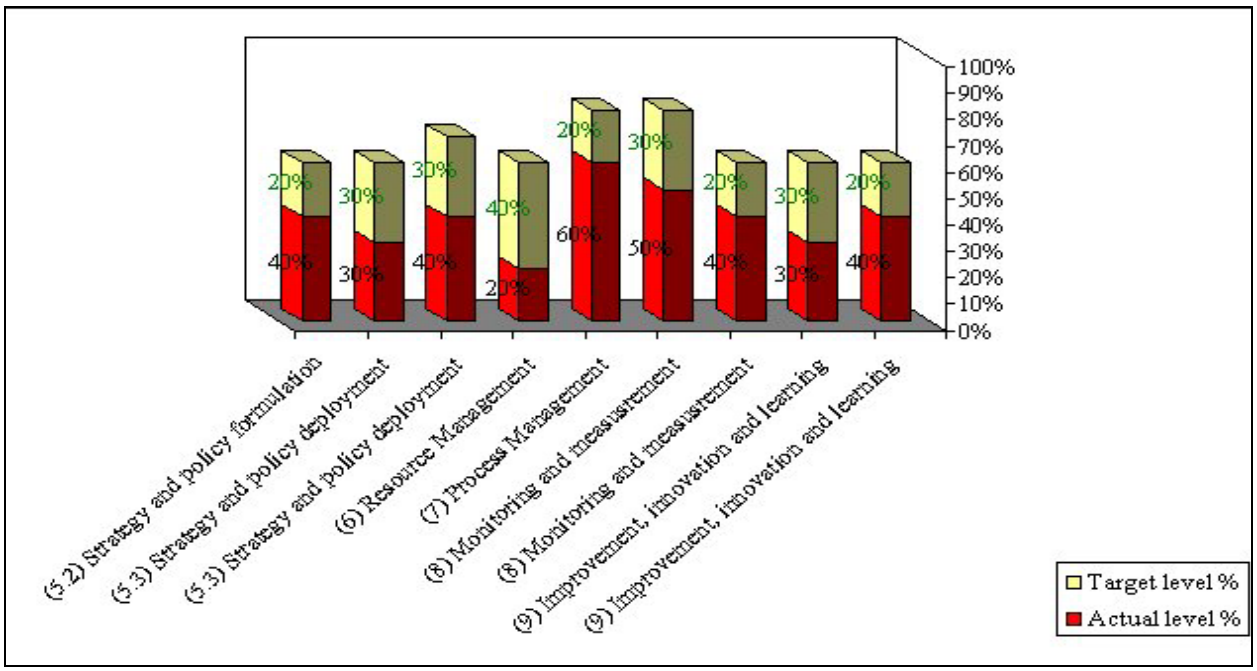
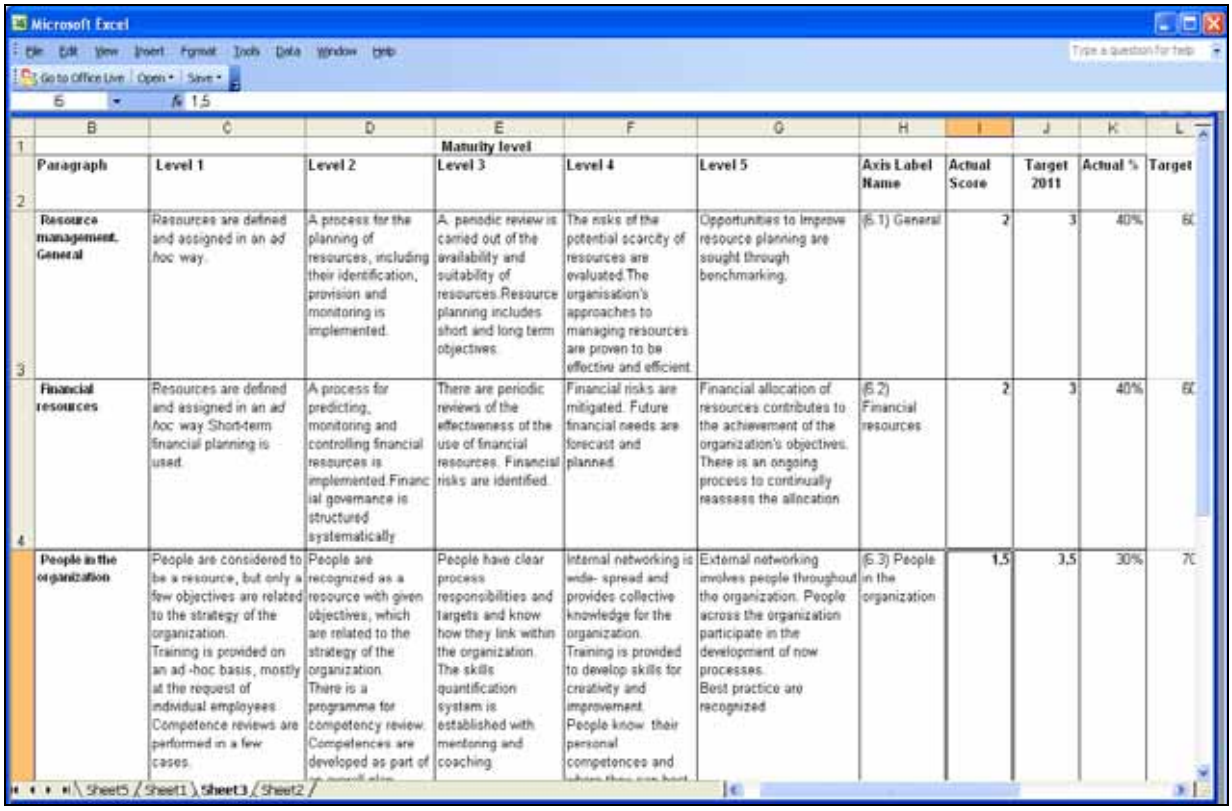


Fig. 4. Graphical result of the strategic self-assessment

As a result, the management should review the strategy and develop a plan to improve the situation regarding the weakness points. To ensure that the improvement plan is effective, it is necessary to identify and adequately analyze and describe the processes involved and the sequence and interactions between them. This step might not be necessary if the organization has already implemented ISO 9001, perhaps at the most would be necessary to re-evaluate these processes, and after that to conduct a self-assessment at an operational (detailed) level.

The results of the self –assessment for Resource Management is presented below (figure 5). We considered this item taking in account that this key element was the identified weakness point. Of course, the detailed self-assessment should be made for each detailed element.



	B	C	D	E	F	G	H	I	J	K	L
1				Maturity level							
2	Paragraph	Level 1	Level 2	Level 3	Level 4	Level 5	Axis Label Name	Actual Score	Target 2011	Actual %	Target
3	Resource management. General	Resources are defined and assigned in an ad hoc way.	A process for the planning of resources, including their identification, provision and monitoring is implemented.	A periodic review is carried out of the availability and suitability of resources.Resource planning includes short and long term objectives.	The risks of the potential scarcity of resources are evaluated.The organisation's approaches to managing resources are proven to be effective and efficient.	Opportunities to improve resource planning are sought through benchmarking.	(5.1) General	2	3	40%	6(
4	Financial resources	Resources are defined and assigned in an ad hoc way.Short-term financial planning is used.	A process for predicting, monitoring and controlling financial resources is implemented.Financial governance is structured systematically.	There are periodic reviews of the effectiveness of the use of financial resources. Financial risks are identified.	Financial risks are mitigated. Future financial needs are forecast and planned.	Financial allocation of resources contributes to the achievement of the organization's objectives. There is an ongoing process to continually reassess the allocation.	(5.2) Financial resources	2	3	40%	6(
	People in the organization	People are considered to be a resource, but only a few objectives are related to the strategy of the organization. Training is provided on an ad -hoc basis, mostly at the request of individual employees. Competence reviews are performed on a few cases.	People are recognized as a resource with given objectives, which are related to the strategy of the organization. There is a programme for competency review. Competences are developed as part of	People have clear process responsibilities and targets and know how they link within the organization. The skills quantification system is established with mentoring and coaching.	Internal networking is wide- spread and provides collective knowledge for the organization. Training is provided to develop skills for creativity and improvement. People know their personal competences and	External networking involves people throughout the organization. People across the organization participate in the development of new processes. Best practice are recognized.	(5.3) People in the organization	1,5	3,5	30%	7(

Fig.5 Results of the self –assessment for Resource Management

Analyzing the graphic result (figure 6), we can conclude that the organization should focus on improving the human resources and infrastructure management.

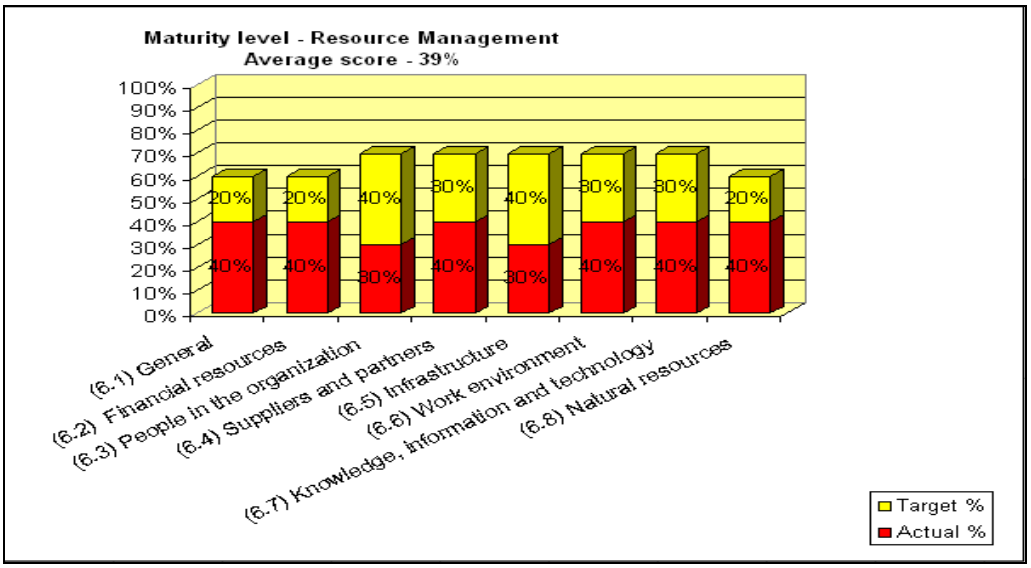


Fig.6 Maturity level for Resource Management

The decision regarding the actions needed to improve the human resources and infrastructure management should be taken on a profound analysis, including a risk assessment. Some results of risk management process applied for infrastructure is presented bellow.

3.1 Risk Identification

To identify the risks associated with the infrastructure, the organisation should identify first the infrastructure items (table 1), and for each item should identify sources of risks, events, causes or sets of circumstances [2] related to the item and their potential consequence on the established targets (table 2).

The values of the infrastructure items are selected using the following range:

- I - insignificant
- Mi - minor
- Mo - moderate
- Ip - important
- H - high
- VH - very high
- C - critical

For each infrastructure item, it should be made a risk analyse and evaluation to establish the risk exposure and the strategy to treat the risk. The scales used for analyse are as follow:

Likelihood:

1 - Extremely low
2 - Very low
3 - Low
4 - Moderate
5- High
6 - Very high

Impact:

1 - Insignificant
2 - Minor
3- Moderate
4- Important
5 - High
6 - Very high
7 - Critical

Table 1 - **Infrastructure register – sample**

A	B	C	D	E	F	G	H
Infrastructure	**Items description**	**Item ID**	**Location**	**Owner**	**User**	**Value**	**Registration date**
Buildings, utilities	Office building	I-01	Address, Map A	Rresponsible for maintenance	All	VH	05.01.2011
	Workspace	I-02	Address, Map B	Rresponsible for maintenance	All	VH	05.01.2011
	Warehouse	I-03	Address, Map C	Rresponsible for maintenance	All	H	05.01.2011
	Water	I-04	Address	Rresponsible for maintenance	All	VH	05.01.2011
	Electricity	I-05	Address	Rresponsible for maintenance	All	VH	05.01.2011
Process equipments	CNC lathe	II-01-01	Cutting department, B1, ground floor	Rresponsible for maintenance	Turner	M	05.01.2011
	CNC lathe	II-01-02	Cutting department, B1, ground floor	Rresponsible for maintenance	Turner	M	05.01.2011
	Drilling machine with rotary table	II-02-01	Cutting department, B1, ground floor	Rresponsible for maintenance	Drill operator	M	05.01.2011
	Screw machine with rotary table	II-03-01	Cutting department, B1, ground floor	Rresponsible for maintenance	Threading processor	M	05.01.2011
	Shell end mill	II-04-01	Cutting department, B1, ground floor	Rresponsible for maintenance	Miller	M	05.01.2011
	Galvanizing Lines	II-20-01	Painting - electroplating department, B2	Rresponsible for maintenance	Electroplating operator	M	05.01.2011
		II-20-02	Painting - electroplating department, B2	Rresponsible for maintenance	Electroplating operator	M	05.01.2011
	Electrostatic painting plant	II-21-01	Painting - electroplating department, B2	Rresponsible for maintenance	Painting operator	H	05.01.2011
	Wastewater treatment plant	II-30 -01	Address, Map D	Rresponsible for maintenance	Oparator	VH	05.01.2011
Support services	Transportation	III-01	Address	Procurement responsible	Delivery department	M	05.01.2011
	Communications	III-02	Address	Procurement responsible	All	H	05.01.2011

Infrastucture Register | Infrastructure Risk Register | Sheet3

The exposure risk is established using the table no. 2 and the acceptable level of risk was defined at 3.5.

Table 2- **Exposure risk matrix**

	Impact						
Likelihood	**Insignificant (1)**	**Minor (2)**	**Moderate (3)**	**Important (4)**	**High (5)**	**Very high (6)**	**Critical (7)**
Very high (6)	1	3	4	5	6	7	7
High (5)	1	3	4	5	5	6	7
Moderate (4)	1	2	3	4	5	6	6
Low (3)	1	2	3	4	4	5	5
Very low (2)	1	2	2	3	4	4	4
Extremely low (1)	1	1	2	2	3	3	3

An example of such analyse is presented in table 3. As can be seen from the example given - a CNC lathe, as part of the infrastructure, some hazards have been identified with unacceptable level of risk, such as:

- Failure, due to wear
- Mechanical hazards, due to hazardous moving parts
- Electrical hazards, due to defective plugs or switches, cables with damaged insulation
- Misadjusted equipment, due to frequent adjustment required

Table 3 - **Risks Register - sample**

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
Risk Area	**Targets**	**Risk description**	**Circumstances that favour the risk (causes)**	**Risk management responsible (s)**	**Existing Control**	**Inherent Risk**				**Control tool / method**	**Residual Risk**			**Remarks**
						Likelihood	**Impact**	**Risk Exposure**	**Adopted strategy**		**Likelihood**	**Impact**	**Risk Exposure**	
Infrastructure / CNC lathe II-01-01	Dependability	Failure	Wear	Production Technician	Maintenance program	3	5	4	Immediate treatment	Weekly preventive maintenance	1	5	3	Risk accepted and monitoring
		Inadequate maintenance logistics	Insufficient resources	Production Technician	Expenditure budget	1	6	3	Risk accepted. Medium-term monitoring					
	Decreasing the number of incidents / accidents	Mechanical hazards	Hazardous moving parts	H&S resp.	Transparent protection screen and emergency button	3	5	4	Immediate treatment	Check the integrity and functionality of protection screen and guards and immediate remedy failures	1	5	3	Risk accepted and monitoring
		Electrical hazards	Defective plugs or switches, cables with damaged insulation	H&S resp.	Periodical check of electrical system	2	7	4	Immediate Treatment	Regularly check electrical wiring, replacement of defective switches or plugs	1	7	3	Risk accepted and monitoring
	Waste Reduction	Misadjusted equipment	Frequent adjustment required	Production Technician	Adjustment every 4 hours	4	4	4	Immediate Treatment	Adjustment every 2 hours	2	4	3	Risk accepted and monitoring

Infrastucture Register | **Infrastructure Risk Register** | Sheet3

For all these hazards it was decided to immediately take actions aimed to reduce the probability of occurrence of the circumstances that favour those risks. As can be seen, the residual risk obtained after implementation of these measures was below the acceptable risk.

Overall risk level (ORL) for each element of infrastructure is calculated as a weighted average of risk levels established for the identified risk factors. To make the results to reflect reality as accurately as possible, the risk level will be used as a weighting factor. In this way, it will be eliminated the compensation effect between extremes [4].

The risk levels for all hazards identified for the CNC lathe (identification no. II-01-01) are presented in figure 7. In a similar way was established the overall risk level for infrastructure, the established value being 3.41.

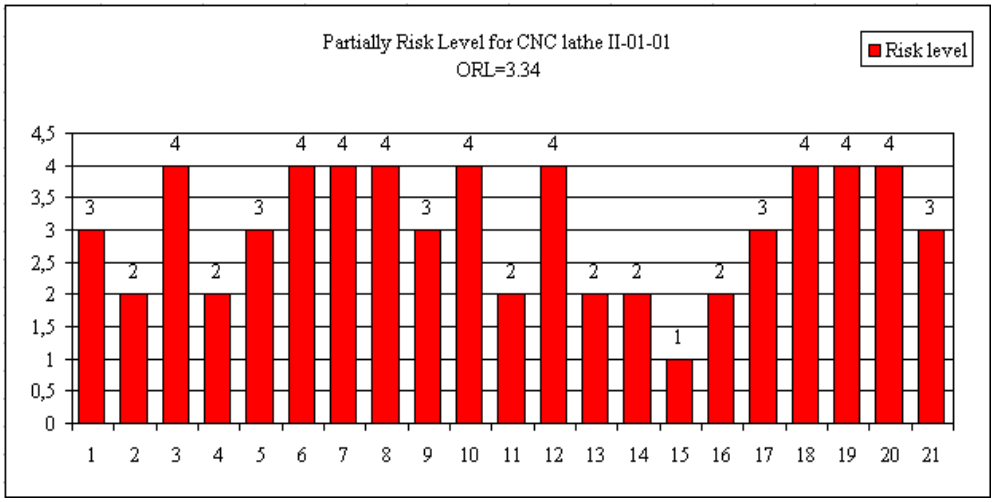


Fig.7 Risk levels for hazards identified for the CNC lathe

3.2 Risk Treatment and management decisions

As a result of risk assessment process for infrastructure, the management can take a right decision about how to improve the weakness point, by developing and implementing a adequate treat risk plan, for short term horizon, as follow (table 4) and by developing a management agenda and action plans for the medium term horizon (2-3 years):

Table 4 - **Treat risk plan –Infrastructure - sample**

Crt. No.	Risk area/ Hazard description / Circumstances that favour the risk (causes)	Risk level	Reduction Method	Responsible	Application
1.	CNC lathe II/01/01 / failure / wear	4	Preventive maintenance	Production Technician	Weekly
2.	CNC lathe II/01/01 / Mechanical hazards / Hazardous moving parts	4	Check the integrity and functionality of protection screen and guards and immediate remedy failures	H&S resp.	Weekly
3.	CNC lathe II/01/01 / Electrical hazards / Defective plugs or switches, cables with damaged insulation	4	Regularly check electrical wiring, replacement of defective switches or plugs immediately by authorized persons	H&S resp.	Monthly
4	CNC lathe II/01/01 / Misadjusted equipment / Frequent adjustment required	4	Increase adjustment frequency	Production Technician	Every 2 hours

Starting from the analysis made the medium-term priorities in the organization have been defined as follow:

- Implement a system for planning and efficient use of resources
- Implement a system to recognize and motivate employees
- Implement an IT system for customer relationship management

The progress achieved by implementing all these actions set out after the initial self-assessment was reviewed at the next self assessment (figure 8).

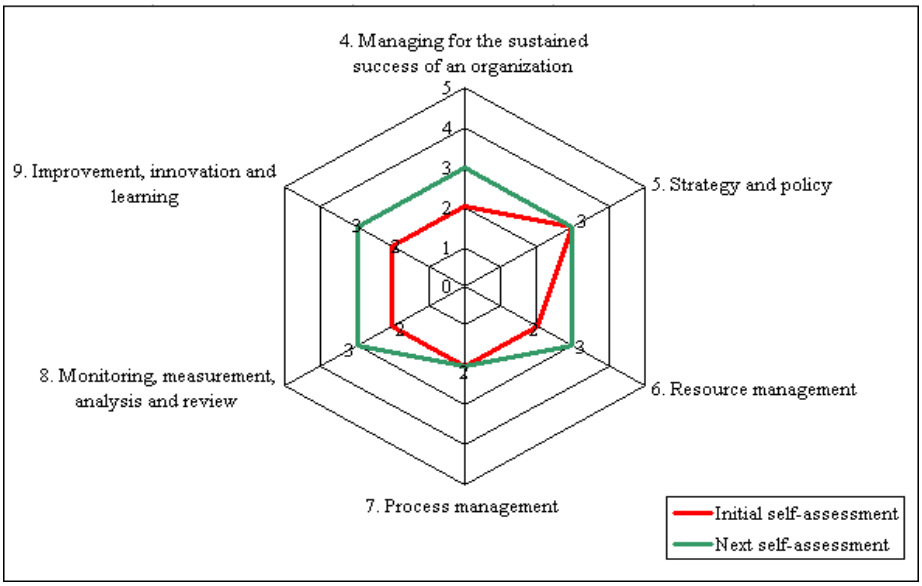


Fig.8 Comparative results of self-assessments

4. Conclusions

The integration of risk assessment as a core of an integrated management system – quality, environmental, health and safety and using ISO 9004: 2009 for self – assessing the maturity level allowed the company to identify the weakness points and to develop the medium-term strategy of the organization.

B I B L I O G R A P H Y

[1] *** ISO 9004, Managing for the sustained success of an organization -- A quality management approach, ISO, Geneva, 2009
[2] *** ISO 31000, Risk management -- Principles and guidelines, ISO, Geneva, 2009
[3] *Liliana Nitu, Lucian Nitu,* Integrated Risk Management as a core of an Integrated Management System, 54th EOQ Congress, Izmir, Turkey, 26- 27 October, 2010
[4] *Darabont, Aexandru, Pece Şefan, Dăscălescu Aurelia,* Managementul securităţii şi sănătăţii în muncă, Editura AGIR, Bucureşti, vol. I – II, 2001