

# ISO 45001:2018

## Changes and requirements



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# Presentation structure



EHSEC

● **Introduction**

● **Integration of Management systems**

● **Risk - Based Thinking**

● **ISO 45001:2018**

● **Discussion**

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# Who are we...?

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**Q & S department was established in 2001 y.**

**Education in 2 separate study programmes:**

- Quality Production
- Safety of technical systems

**National and international projects (included 7FP - IntegRisk)**

**External cooperation:**

- Risk Analysis (SEVESO, OH&S, Pipeline integrity, ATEX)
- Management Systems - *implementation* (BBS)
- Maintenance Management (RCMCost, TPM, FMEA, ...)



# Department Activities

*„Becoming an expert is essentially being willing to start with nothing”*

National projects, Structural funds,  
Erasmus programs, 7FP

## RESEARCH



Bc., MSc., PhD.

## EDUCATION



## COOPERATION



EHSEC

embraco



ŠKODA



ur-shin



GETRAG

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# VUCA Time

Source: <http://robertjgardner.co.uk/2013/07/22/vuca-the-acronym-of-our-time/>



„... it is profoundly changing not only how organizations do business, but how leaders lead and how pension funds are managed. The skills and abilities leaders once necessary to thrive are no longer sufficient or even applicable.“

# EU - Direct costs of accident

Major accident (MA): human life, environment, property

~ 30 MA/year **X** > 150 mil. €/accident



Total 4 500 000 000 EUR / year

OH&S: Life and ill health

> 2,3 mil. human death / year

=

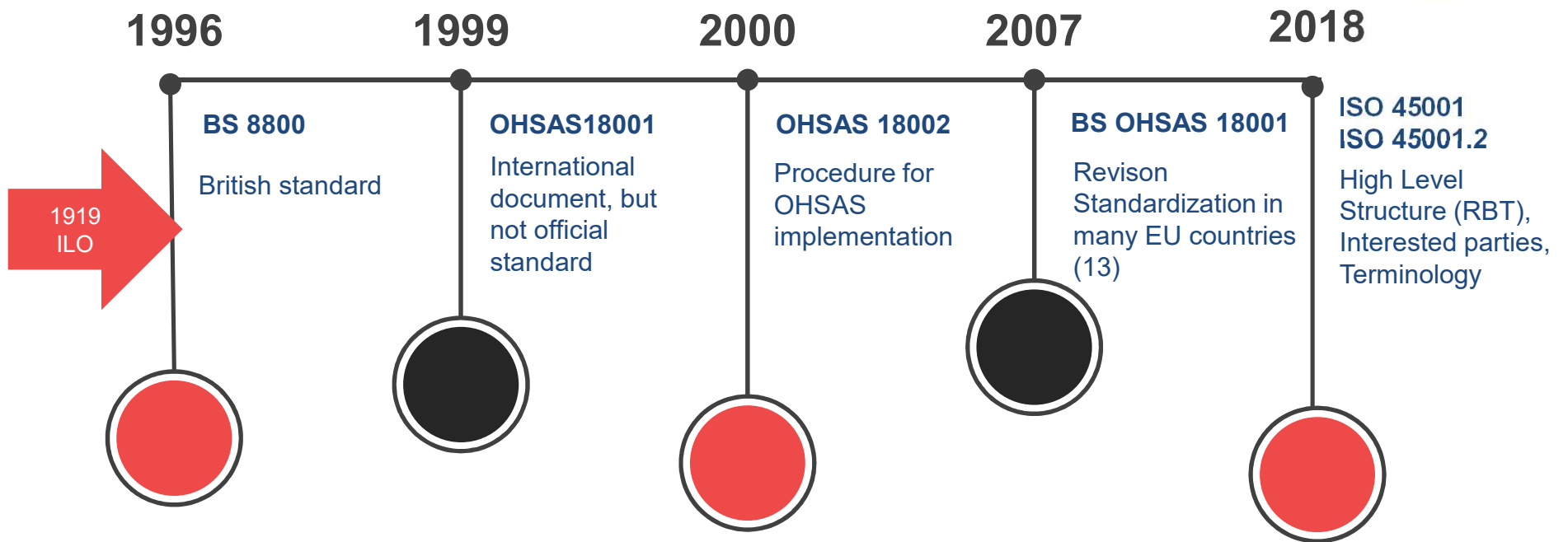
Total cost for the economy: 3 trillion EUR / year





# Safety Management System

History

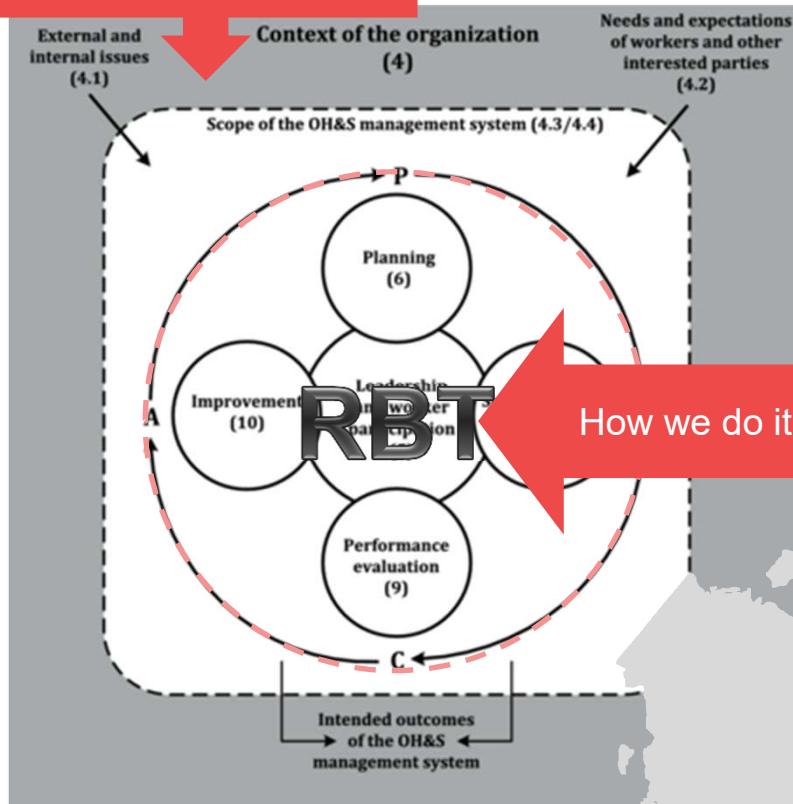


# ISO 45001:2018

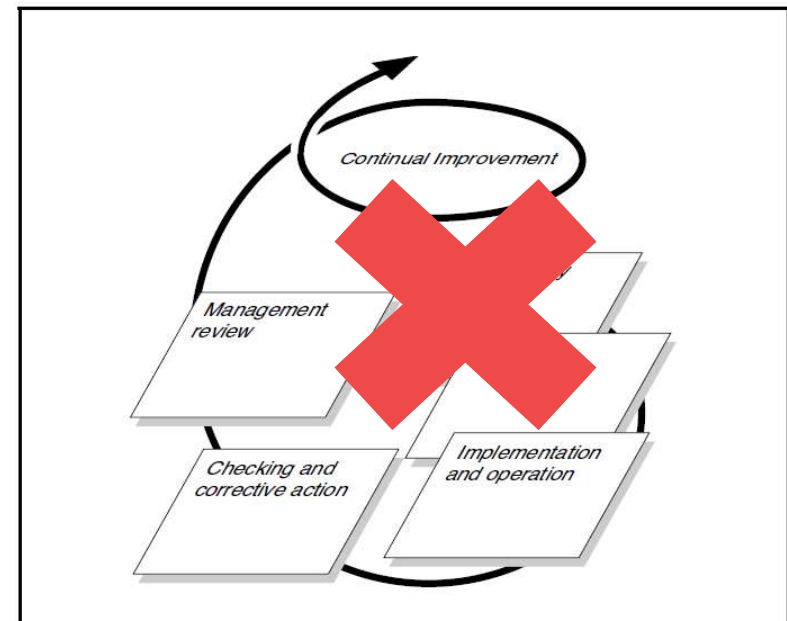


Where are we  
and who are we?

Developed by ISO – process started in y. 2016



How we do it?





# ISO 45001:2018

Different from OHSAS structure



## NEW ELEMENTS

- ✓ High Level Structure (HLS- Annex SL)
- ✓ Risk-Based Thinking (RBT)
- ✓ Involved of interested parties
- ✓ OHS opportunity
- ✓ Terms and definition – *new and revised*
- ✓ ~~Preventive action~~
- ✓ Process approach
- ✓ Documented information
- ✓ Outsourcing
- ✓ ...

## REMAIN ELEMENTS

- ✓ PDCA
- ✓ Continual improvement

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## Appendix C1



# 10 Chapters

Annex SL



	BS OHSAS 18001		ISO 45001
1.	Scope	1.	Scope
2.	Normative References	2.	Normative References
3.	Terms and Definitions	3.	Terms and Definitions
4.	OH&S management system Requirements	4.	Context of the Organization
4.2	OH&S Policy	5.	Leadership
4.3	Planning	6.	Planning
4.4	Implementation and operation	7.	Support
	4.4.6 Operational Control	8.	Operation
4.5	Checking	9.	Performance Evaluation
4.6	Management Review		
		10.	Improvement
	Annex A, Annex B		Annex A

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# Scope

	ISO 45001
1.	Scope
2.	Normative references
3.	Terms and Definitions
4.	Context of the Organization
5.	Leadership
6.	Planning
7.	Support
8.	Operation
9.	Performance evaluation
10.	Improvement

This International Standard specifies requirements for an OH&S MS, with guidance for its use, to enable an organization to provide safe and healthy working condition for the prevention of work-related injury and ill health and to **proactively** improve its **OH&S performance**.

This includes the development and implementation of an OH&S policy and objectives which take into account applicable legal requirement and other requirement to which the organization subscribes.

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# Terms and Definition

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For the purpose of this document, the following **37 terms and definition** are applied.

ISO 45001:2018		BS OHSAS 18001	
3.1	Organization – <i>different</i>	3.17	Organization
3.2	Interested parties – <i>different</i>	3.10	Interested parties
3.3	Worker		
3.4	Participation		
3.5	Consultation		
3.6	Workplace	3.23	Workplace
3.7	Contractor		
3.8	Requirements		
3.9	Legal requirements and other requirements		
3.10	Management system		
3.11	OH&S management system	3.13	OH&S management system
3.12	Top management		
3.13	Effectiveness		
3.14	Policy		
3.15	OH&S policy	3.16	OH&S policy
3.16	Objective		
3.17	OH&S objective	3.14	OH&S objective
3.18	Injury and ill health – <i>different</i>	3.8	ill health
3.19	Hazard	3.6	Hazard



23 terms

37 terms



3.20	Risk ( <i>effect of uncertainty</i> ) – <i>different</i>	3.21	Risk
3.21	OH&S risk		
3.22	OH&S opportunity		
3.23	Competence		
3.24	Documented information – <i>different</i>	3.20	Record, document (3.5)
3.25	Process		
3.26	Procedure	3.19	Procedure
3.27	Performance		
3.28	OH&S performance – <i>different</i>	3.15	OH&S performance
3.29	Outsource		
3.30	Monitoring		
3.31	Measurement		
3.32	Audit	3.2	Audit
3.33	Conformity		
3.34	Nonconformity	3.11	Nonconformity
3.35	Incident	3.9	Incident
3.36	Corrective action	3.4	Corrective action
3.37	Continual improvement	3.3	Continual improvement
		3.1	Acceptable risk
		3.12	OH&S
		3.18	Preventive action
		3.22	Risk assessment



# Terms and definitions

<b>ISO 45001:2018</b>		<b>BS OHS 18001</b>	
3.20	Risk (effect of uncertainty) - different	3.21	Risk (combination of the likelihood of an occurrence of a hazardous event or exposure and the severity of injury or ill health that can be caused by the event or exposures)
3.21	OH&S risk (combination of the likelihood of occurrence of a work-related hazardous event or exposure and the severity of injury or ill health that can be caused by the event or exposures)		
3.22	OH&S opportunity (circumstance or set of circumstances that can lead to improvement of OH&S performance)		
		3.12	OH&S
		3.18	Preventive action
		3.22	Risk assessment

# Context of the Organization

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External and internal issue – boundaries – documented

Process approach

## 4.1 Understanding the organization and its context

*The organization shall determine **external and internal issue** that relevant to its purpose and that affect its ability to achieve the intended outcomes of its OH&S MS.*

## 4.2 Understanding the needs and expectations of workers and other interested parties

- ✓ *Workers of other interested parties,*
- ✓ *Workers (own),*
- ✓ *Interested parties which needs and expectation become applicable legal and other requirements.*

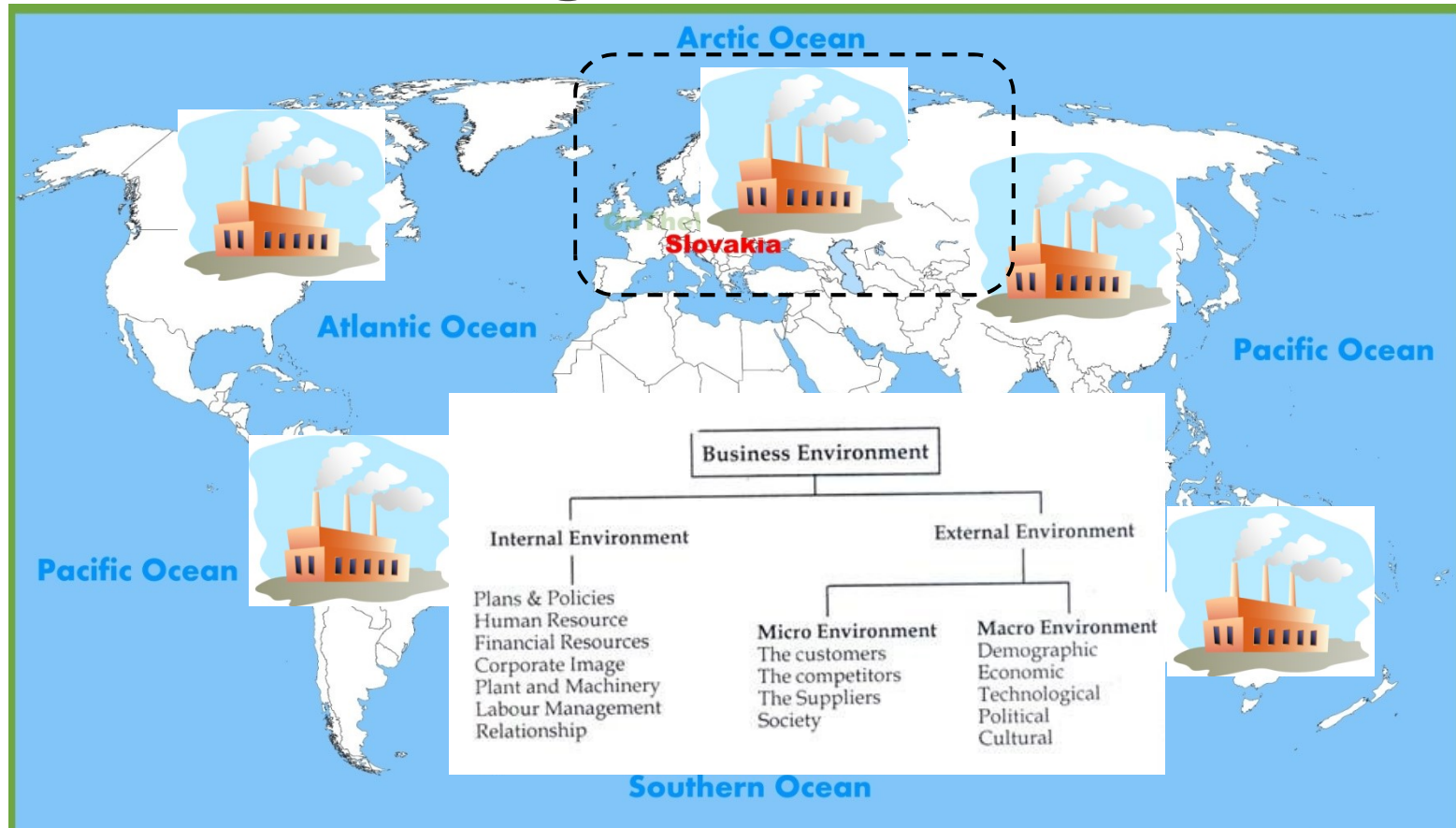
## 4.3 Determining the scope of the OH&S MS

- *Shall determine boundaries and applicability of the OH&S MS – scope shall be available as **documented information**.*

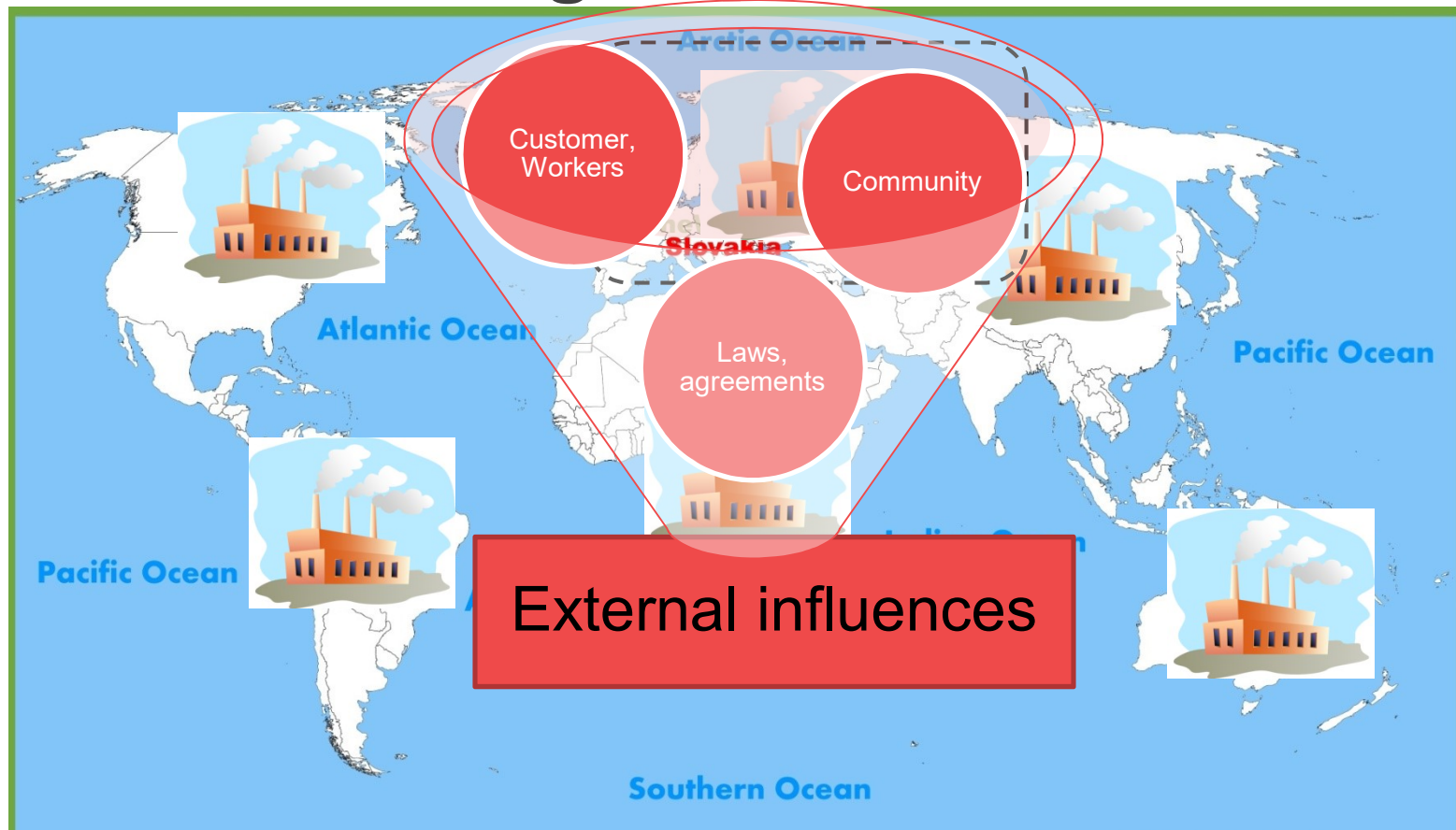
## 4.4 OH&S MS

*The organization shall establish, implement, maintain and continually improve an OH&S MS, including the **processes needed and their interactions**, in accordance with the requirement of this International Standard.*

# Context of the Organization – Where we are?



# Context of the Organization – Where are we?

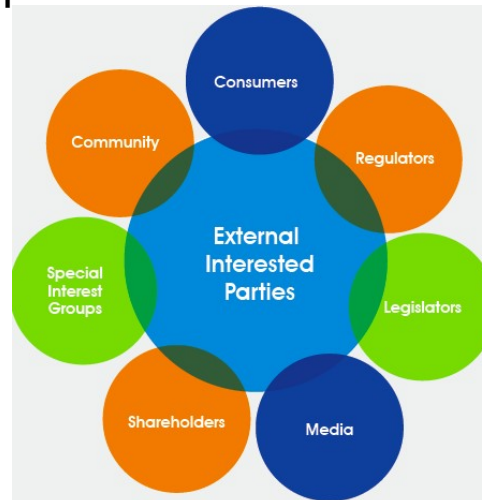


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# Context of the Organization – Where are we?

## External Context Issue

- ✓ Cultural, political economic and legal issues, natural surroundings and market competition
- ✓ New technologies, laws and occupation
- ✓ Key drivers and trends in industry sector (Industry 4.0)
- ✓ Relationship, perceptions and values of external interested parties.



Source: *isr\_dis\_45001*

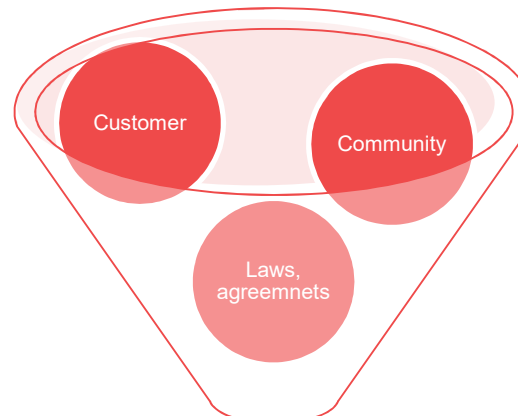
# Context of the Organization – Where are we?

## PESTLE ANALYSIS

P	E	S	T	L	E
Political	Economic	Social/Cultural	Technology	Legal	Environment
<ul style="list-style-type: none"> <li>Stability of Government</li> <li>Potential changes to legislation</li> <li>Global influences</li> </ul>	<ul style="list-style-type: none"> <li>Economic growth</li> <li>Employment rates</li> <li>Inflation rates</li> <li>Monetary policy</li> <li>Consumer confidence</li> </ul>	<ul style="list-style-type: none"> <li>Income distribution</li> <li>Demographic influences</li> <li>Lifestyle factors</li> </ul>	<ul style="list-style-type: none"> <li>International influences</li> <li>Changes in information technology</li> <li>Take up</li> </ul>	<ul style="list-style-type: none"> <li>Taxation policies</li> <li>Employment</li> </ul>	<ul style="list-style-type: none"> <li>Environmental influences</li> <li>Climate change</li> <li>Resource availability</li> </ul>

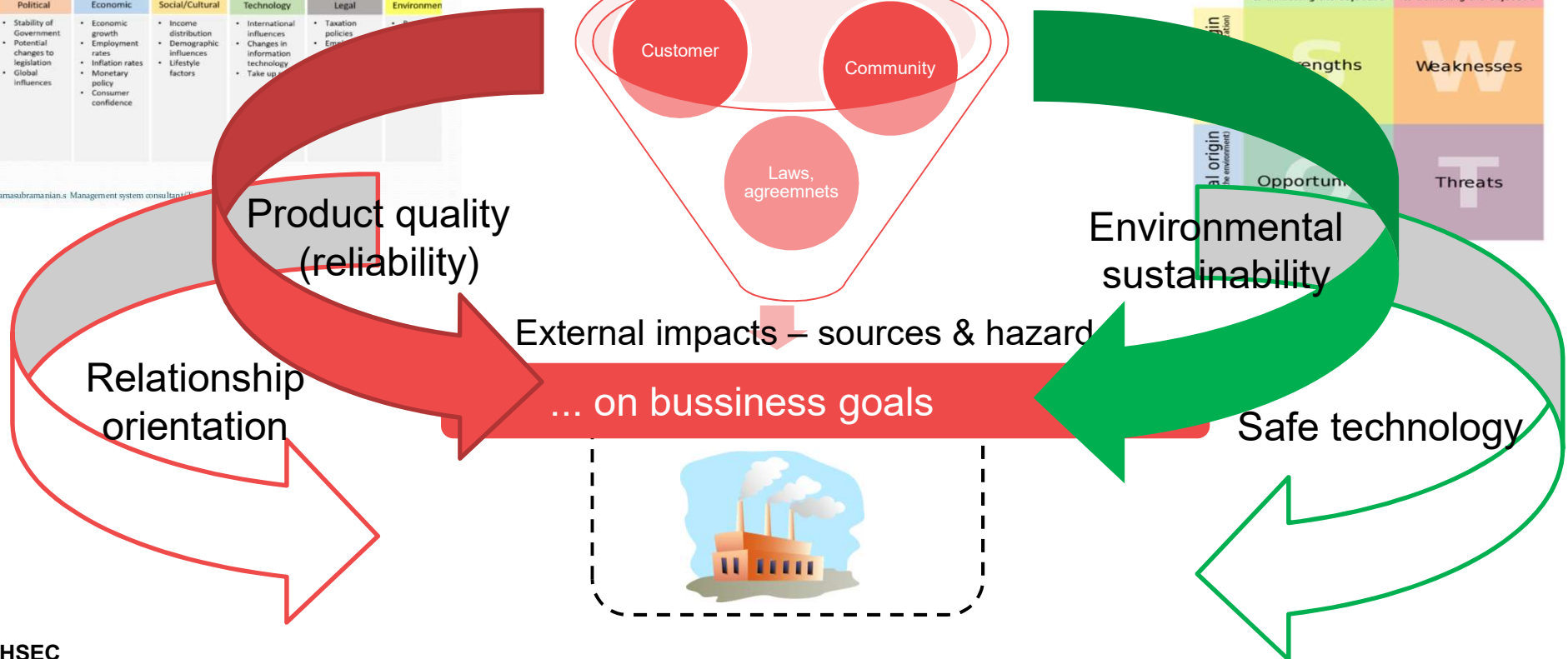
Ramasubramanian's Management system consultant

Frame of external influences - hazards



## SWOT ANALYSIS

Helpful to achieving the objective	Harmful to achieving the objective
Strengths	Weaknesses
Opportunities	Threats



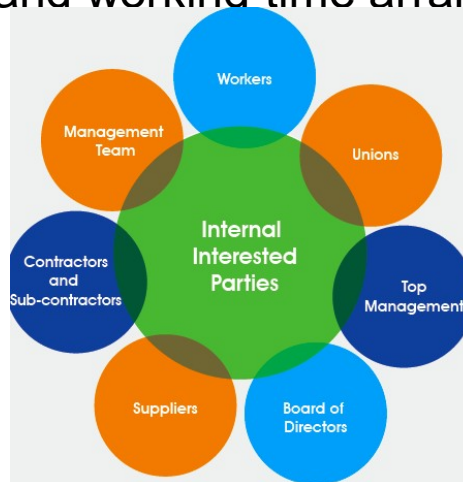


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# Context of the Organization – Who are we?

## Internal Context Issues

- ✓ Organizational structure, roles, accountabilities, capabilities and culture
- ✓ Information systems, flows and decision-making
- ✓ Introduction of new products, materials, services, tools and equipments
- ✓ Standards, guidelines and contractual relationship (outsourcing)
- ✓ Working conditions and working time arrangement.



Source:isr\_dis\_45001

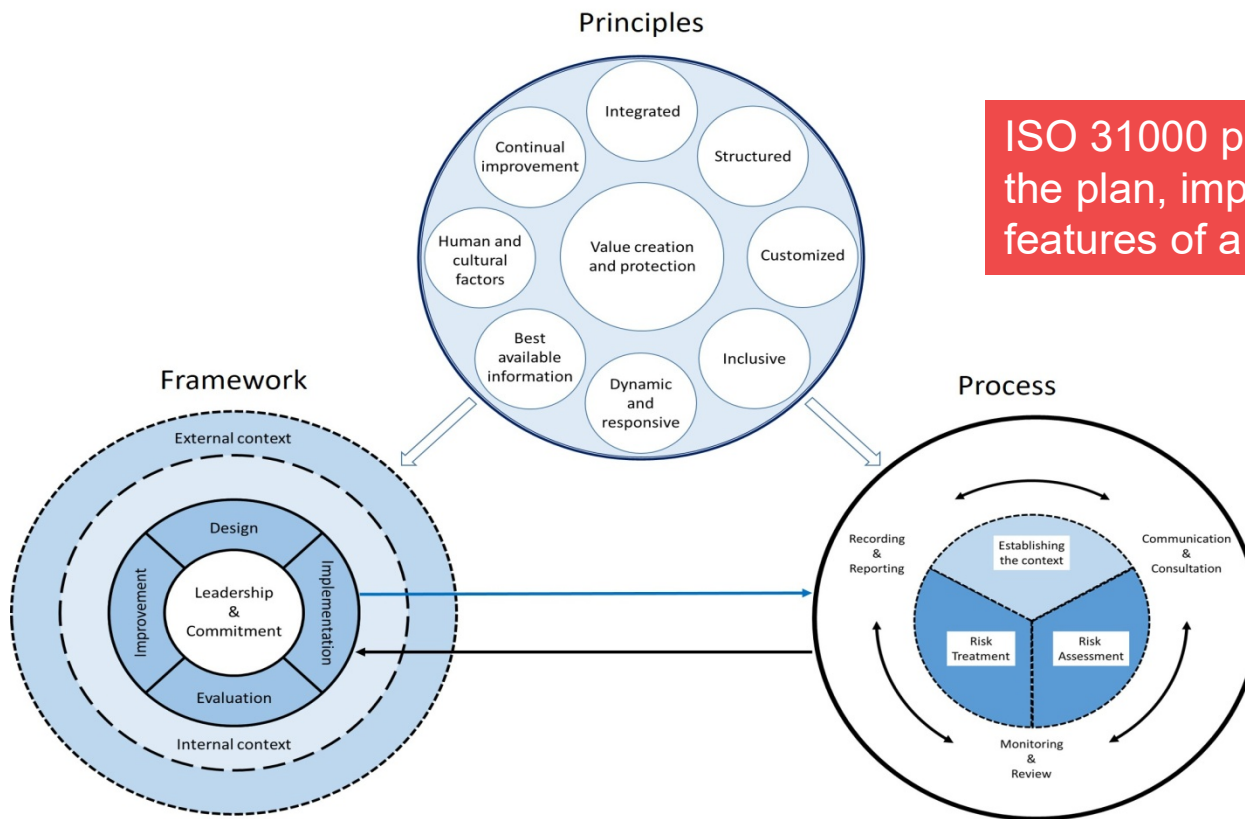
# Risk - Based Thinking (RBT)

ISO 31000:2018 Risk management - Guidelines

*RISK - the effects of uncertainty on Objectives*



# Principles, framework and risk management process from ISO 31000



ISO 31000 provides detailed guidelines on the plan, implement, measure and learn features of a risk management system.



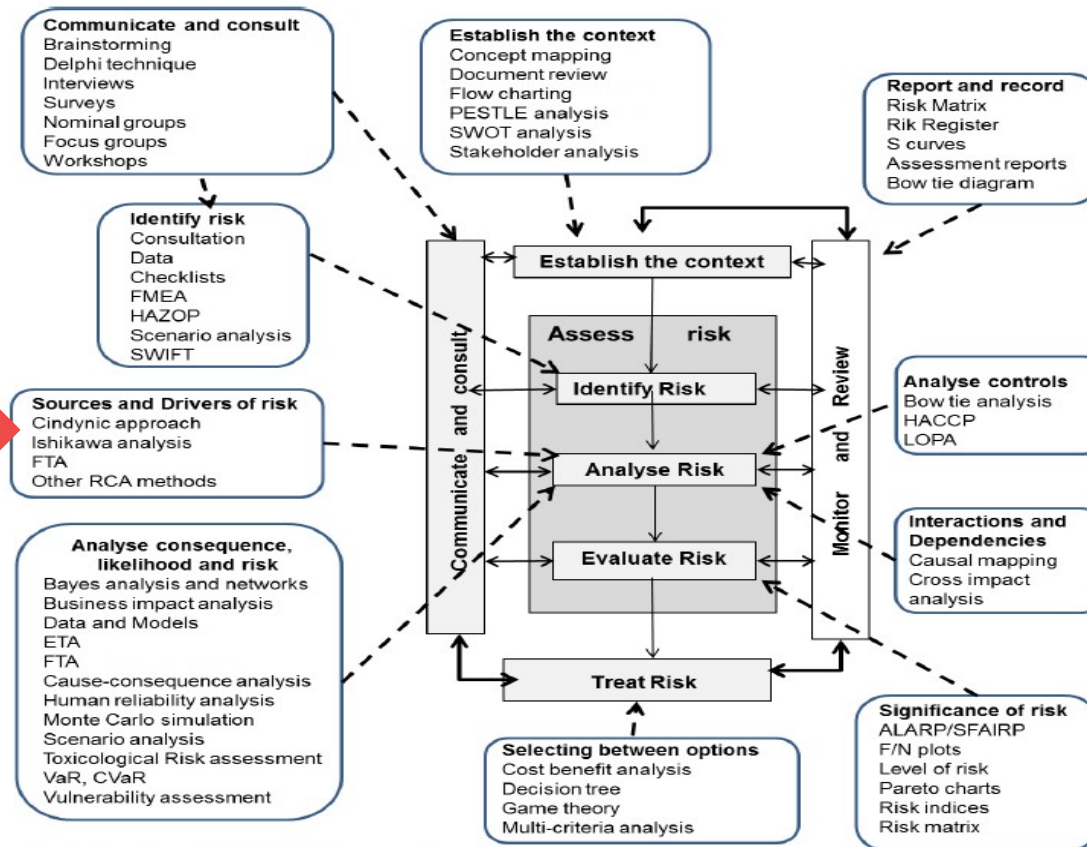
# RBT - Support

ISO 31010

Which are suitable for:

- Quality
- Safety
- Security
- Environment
- Energy
- Continuity
- ...

Risk assessment?



Plan

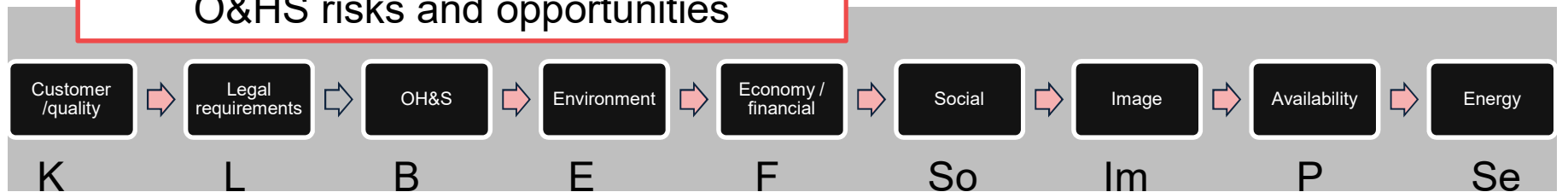
Do

Check

Act

# Context of organization – hazards identification

## O&HS risks and opportunities



Cetghory of Consequecess „C“																				Celkková úroveň rizika
Customer Kvalita (3,2,1)	R(K)	Legiislative (3,2,1)	R(L)	Safety (3,2,1)	R(B)	Environment (3,2,1)	R(E)	Financial (3,2,1)	R(F)	Social (3,2,1)	R(So)	Image (3,2,1)	R(Im)	Availability (3,2,1)	R(P)	Profit(3,2,1)	R(Zi)	Energy( (3,2,1)	R(S)	RSUM
3	9	1	3	2	6	2	6	3	9	2	6	2	6	1	3	3	9	1	3	> 30 vysoká hodnota
																				< ako 16 zanedbateľné

Context of the organization (Source of Risks)			Possible consequences on bussiness goals
Process – ID	Identification hazards//threats	Possibility (1, 2, 3)	
Name of process: MP-01 Management Responsibility			
1.1.	Not clear organization structure and responsibilities.	3 - high	Lack of communication with customers and interested parties, possible high financial losses.

# Context of the Organization – Who are we?



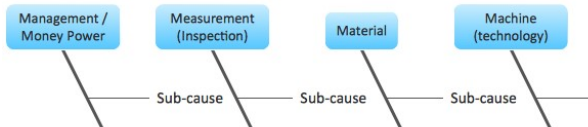
... on business goals

nonconformity

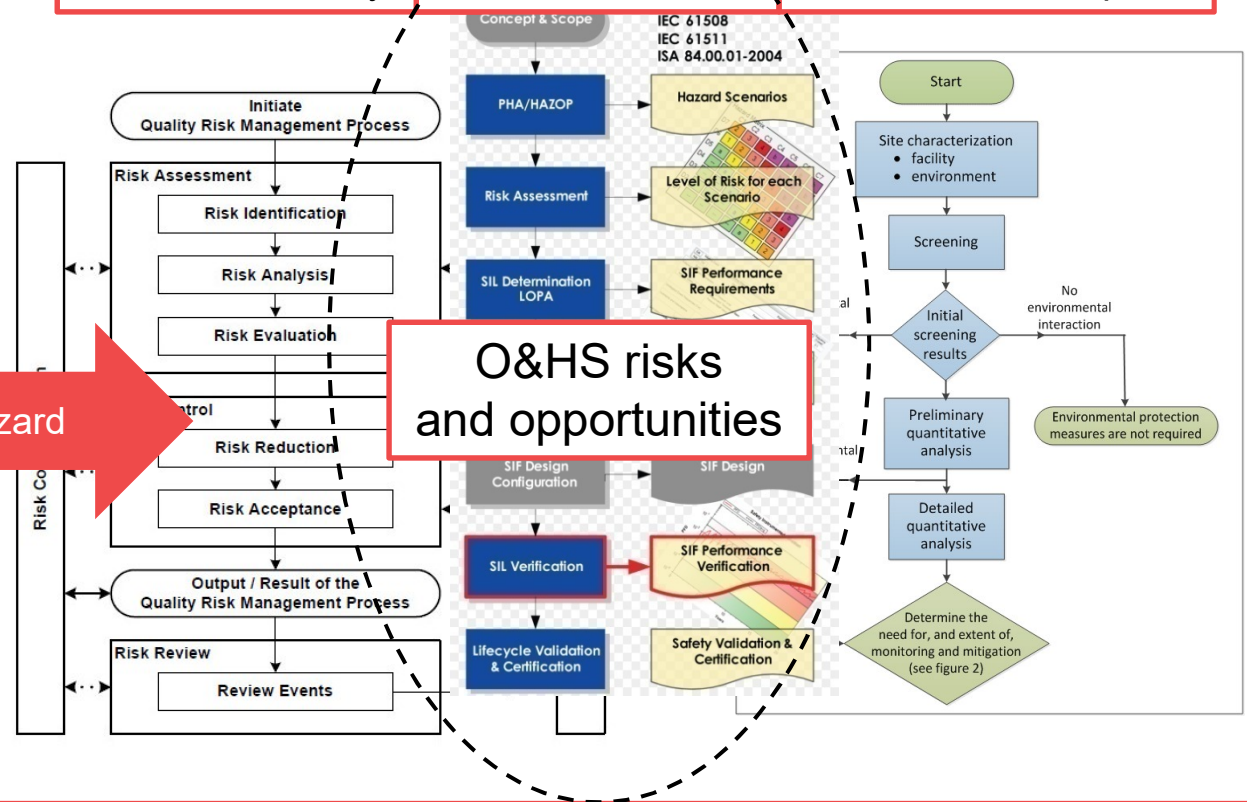
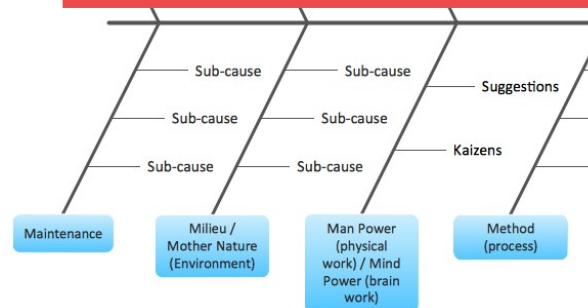
incident, accident

environmental impact

The 8 Ms (used in manufactu



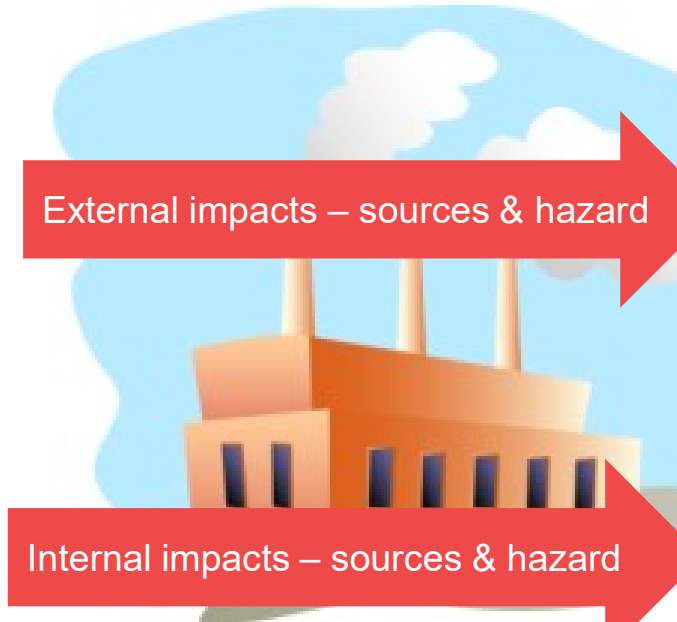
Internal impacts – sources & hazard





# How we do it ?

RBT – Risk register



Risk classes and categories		Hazards	Risk processes			mitigation
			identification	estimation	evaluation	responsibility
Ex	Governance	H1 H2			High	
Ex	Financial	H3			High	
	Regulatory and compliance	H4 H5 H6			Medium	X
In	Operational	H7 H8			Medium	X
In	Safety	H9 H10			High	
	Product	H11			Medium	X

# Leadership and worker participation

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OH&S Culture

Integration OH&S  
into the business  
processes

## 5.1 Leadership and commitments

- *Taking overall responsibility and accountability for the protection of workers' work - related H&S*
- *Ensuring OH&S policy and objectives are established and are compatible with strategic direction*
- *Integration OH&S into the organization's **business processes***
- *Ensuring that the resources for OH&S MS are available*
- *Developing internal/ external communication supporting OH&S*
- *Ensuring OH&S MS achieve intended outcomes, directing and supporting persons to contribute the effectiveness of MS,*
- *Ensuring and supporting continual improvement, OH&S performance by systematically identifying and taking actions to address **nonconformities** and **opportunities**, and work related risks*
- *Developing, leading and promoting an organizational **culture** that support OH&S MS*

## 5.2 OH&S Policy – implement and maintain in consultation with workers at all level of the organization

- ✓ *Commitment– to provide S&H working conditions, appropriate to the purpose, size and context of the organization and **OH&S risks and opportunities***

# Leadership and worker participation

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OH&S Culture

Integration OH&S  
into the business  
processes

## 5.3 Organizational roles, responsibilities, accountabilities and authorities

- *Workers at each level of the organization shall assume responsibility for those aspects of OH&S MS over which they have control*
- *Top management shall assign the responsibility and authority that OH&S MS conforms with ISO standard, reporting performance of MS to top management*

## 5.4 Participation and consultation

- *Organization shall: provide mechanism, time, training and resources for consultation and participation of workers*
- *Identify and remove obstacles or barriers (language literacy barriers, reprisals or threats and policies that discourage or penalize workers participation)*
- *Give additional emphasis to the participation and inclusion of non-managerial workers (risk assessment, communication, expectation of interested parties, establish the policy, assigning organizational role, establish OH&S objectives, determining applicable control for outsourcing, contractors, ... ).*

# Planning

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Proactive Risk  
management

Integration OH&S  
into business  
processes

## 6.1 Action to address risks and opportunities

- When planned OH&S MS the organization based on its context, interested parties, scope (activities) shall determine the OH&S risks and opportunities.
- The organization shall consider the effective participation of workers, where appropriate also involvement of other interested parties
- The organization shall assess the risks and identify the opportunities that are relevant to the intended outcome associated with changes in organizations, its processes or MS. The assessment shall be undertaken before planned changes.
- The organization shall maintain **documented information** about OH&S risks and opportunities, and adequate processes.

### 6.1.2 Hazard identification and assessment of OH&S risks

- Organization shall: establish, implement, maintain a process for the on-going **proactive identification of hazards** arising. Source of hazards could include:
  - ❑ Routine and non-routine activities (equipment, materials, substances, hazard arise from product LC, human factors, work activities)
  - ❑ Emergency situation
  - ❑ Changes – of knowledge, organization, processes, activities, ...
  - ❑ People –workers, contractors, visitors, those who can be affected by organization's activities
  - ❑ Past incidents

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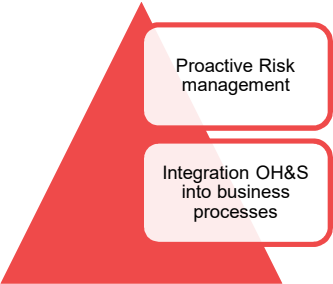
## 6.1.2 Hazard identification and assessment of OH&S risks

### Identification of OH&S and other opportunities

- *Opportunity to enhance OH&S performance (planned changes to organization – processes, activities, opportunities to eliminate or reduce OH&S risk*
- *Opportunities to adapt work – work organization and environment to workers*
- *Opportunities to improving OH&S MS*

Determine of applicable legal requirement and other action

Planning to take action



Proactive Risk  
management

Integration OH&S  
into business  
processes

# Planning

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Proactive Risk management

Integration OH&S into business processes

## 6.2 O&HS objectives and planning to achieve them

- *The objectives shall: be consistent with OH&S policy, legal and other requirements, take into account the result of OH&S and other risks and opportunities, measurable, be monitored, clearly communicated, updated,*
- *Integrated to the business processes*

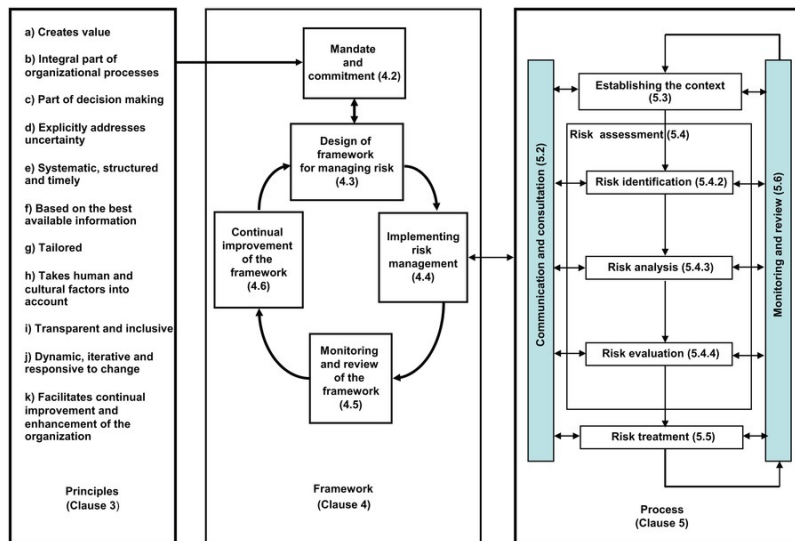
*The OH&S objectives and plans how to achieve them, shall be maintain and retain in **documented information**.*

HAZARD / THREAT						OPPORTUNITY					
R-						R+					
DÔSLEDOK						DÔSLEDOK					
	1	2	3	4	5	5	4	3	2	1	
5	5	10	15	20	25	25	20	15	10	5	5
4	4	8	12	16	20	20	16	12	8	4	4
3	3	6	9	12	15	15	12	9	6	3	3
2	2	4	6	8	10	10	8	6	4	2	2
1	1	2	3	4	5	5	4	3	2	1	1
Negative						Positive					

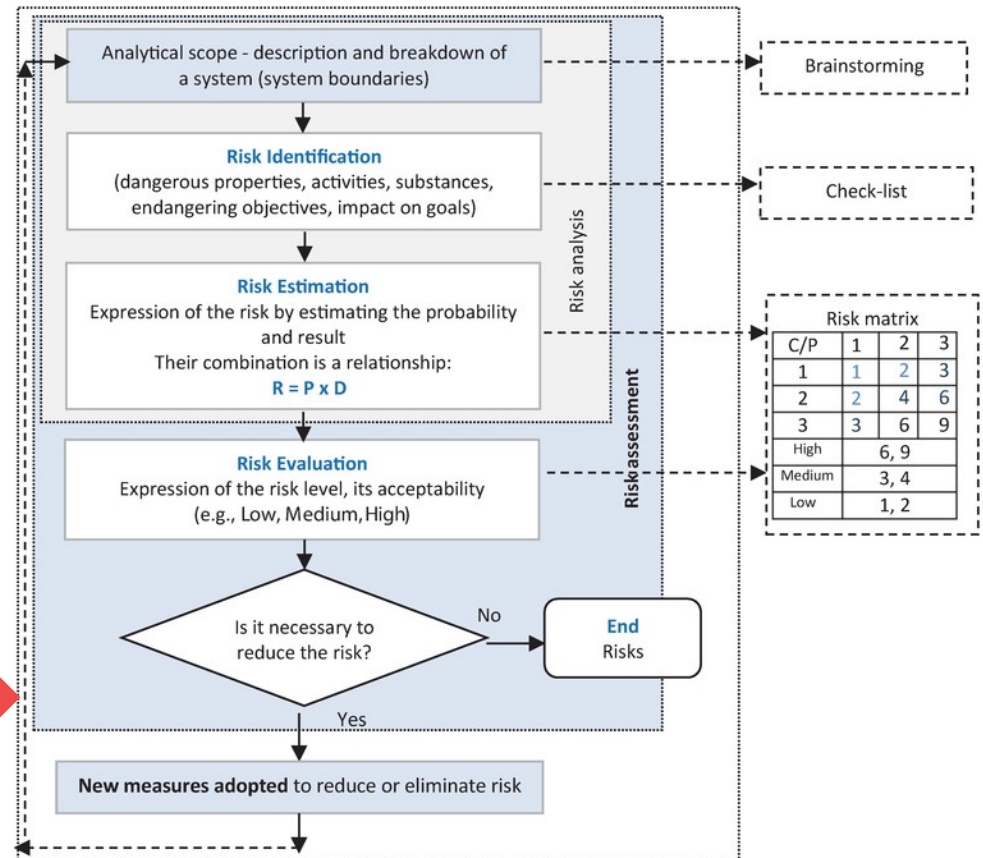


# RBT and OH&S

## RBT to OH&S risk management



From RISK MANAGEMENT to OH&S risk management



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# Support

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Communication,  
workers  
integration

Control of  
documented  
information

## 7.1 Resources

## 7.2 Competence

## 7.3 Awareness of workers


## 7.4 Information and communication (internal and external)

## 7.5 Documented information

- *Available and suitable for use*
- *Adequately protected (loss, confidentiality, use, integrity)*
- *Control (distribution, storage, control of changes, retention and disposal, access by workers.*

# Operation

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Risk control hierarchy

Outsourcing Contractors

## 8.1 Operation planning and control

*Implementation and control the processes needs to meet requirements of the OH&S MS*

### 8.1.2 Hierarchy of controls

- *eliminate the hazards,*
- *substitute with less hazardous materials, processes, operations or equipment,*
- *use engineering control ,*
- *use administrative controls,*
- *provide and ensure use of adequate personal protective equipment.*

## 8.2 Management of change

### 8.3 Outsourcing

*The organization shall ensure that outsourced processes affected its OH&S MS are controlled!*

## 8.4 Procurement of goods (*new equipment, materials*)

### 8.5 Contractors

*The organization shall establish processes to identify and communicate the hazards and evaluate and control risks (contractor´s workers activity, organizational activity and its influence to the contractor´s workers)*

## 8.6 Emergency preparedness and response

# Performance evaluation

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Measuring KPI  
Audit

Effectiveness

## 9.1 Monitoring, measurement, analysis and evaluation (KPI)

- *Criteria against which the organization will evaluate OH&S performance*
- *Methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results (legal and other compliance, hazard identification, operational controls, objectives)*
- *When the monitoring and measuring will be performed*
- *When the results from monitoring and measurement will be analyzed, evaluated and communicated*

## 9.2 Internal audit

- *Planned intervals to provide internal audit – ensure that relevant audit findings are reported to relevant workers, relevant interested parties*

## 9.3 Management review

- *Planned intervals to ensure continuing suitability, adequacy and **effectiveness** of OH&S MS.*

# Improvement

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Hierarchy of  
risk control

Effectiveness

## 10.1 Incident, nonconformity and corrective action

*The organization shall plan, establish, implement, and maintain a process to manage incidents and nonconformities including reporting, investigating and taking action*

- *React in a timely manner to the incident and nonconformity – direct action*
- *Evaluate the participation of workers and the involvement of other relevant interested parties, the need for corrective action to eliminate **the root cause of the incident or nonconformity***
- *Review the OH&S risk assessment*
- *Apply hierarchy of controls and the management of changes in corrective action*
- *Review the effectiveness of any corrective action*

## 10.2 Continual improvement

- *The organization shall continually improve the suitability, adequacy and effectiveness of OH&S MS.*

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This contribution was created by the implementation of APVV-15-0351 project of "Development and Application of a Risk Management Model in the Setting of Technological Systems in Compliance with Industry 4.0 Strategy" and VEGA project no. 1/0150/15 of Development of Methods of Implementation and Verification of Integrated Systems Safety Systems for Machines, Machine Systems and Industrial Technologies.