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Strategic Risk Management and Business Continuity Solutions

- for Enterprises and Business Units
- for Global Supply Chains
- And Individual Product Manufacturing

The amended ISO 9001 : 2015 and the Risk-based approach

What is Risk-based thinking? And what does it achieve?

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„ **Risk** is like fire:

If controlled it will help you;

if uncontrolled it will rise up and destroy you.”

Theodore Roosevelt

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and the Risk-based approach

Agenda:

- What has changed with ISO 9001:2015? And what are the effects of these changes?
- What does the risk-based approach of ISO 9001:2015 mean? (And does the risk-based approach replace the previous process approach?)
- What's the relationship between risk and quality management according to ISO 9001:2015?
- What is risk anyway? And where does it come from?
- Which tools may be helpful? (How does a risk management process work?)
- How can the risk-based approach make a difference in the continuous improvement process?

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Focus of the ISO 9001's latest edition

- ISO 9001 remains to be THE universally accepted, consistent, global standard for quality with it's 2015 update.
- The amended standard emphasizes even more the processes of service provision, same as in the 2000 and 2008 revisions.
- This moves the standard even further away from it's historical focus on procedures and documentation

*The **most important novelty** in the 2015 revision of ISO 9001 is the formal introduction of the "Risk-Based Approach" as*

- *a **systematic starting point for the consideration of risk**, i.e. "Risk-based thinking" as pointed out in Appendix A.4*
- *(replacement of "Prevention" - formerly a separate section)*

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Focus of the ISO 9001's latest edition (continued)

Other significant changes:

- Application of the High Level Structure
- Structuring into 10 sections (instead of 8)
- Increased requirements for senior management
- Consideration of the "context of the organization"
- Consideration of "customers and interested parties"
- Elimination of terms such as "Quality Management Manual", "documented procedures" and "records" in favor of "documented information"
- Naming "Risk" also in other clauses and appendices to give that term a higher relevance for the entire standard

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and the Risk-based approach

Why does the revised ISO 9001 focus specifically on risk?

Risk is connected to both, operational as well as strategic activities in an organization's day-to-day practice.

- The standard recognizes that risk affects all aspects of the quality management system (systems, processes, functions) and its implementation.

- With the statement that "risk-based thinking is something we all do automatically in daily life," ISO strongly refers to the inclusion of common sense, too.

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Why Risk-based thinking?

- Risk-based thinking should lead to risk recognition, then to consideration and controlling of risk.

- By taking risk into account throughout the system and in all processes:
  - the probability of achieving certain objectives shall be improved
  - the results shall become more consistent and
  - customers should become more confident to receive the product or service as expected

- Risk-based thinking introduces the concept of risk as an integral part of the standard:
  - In earlier versions of ISO 9001, a Preventive clause was put separately; now with the Risk-based approach instead, forward-looking prevention shall be an integral part of the entire standard.

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Where are the roots of "Risk-based thinking" in ISO 9001: 2015?

Introduction	"Risk-based thinking" - the concept is explained
Clause 6	The organization is required to identify risks and opportunities related to performance of the quality management system and take appropriate actions to address them
Annex A.4	The Standard specifies requirements for the organization to understand its context and determine risks as a basis for Planning. This represents the application of risk-based thinking to planning and implementing quality management system processes...

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Recommendations of the ISO for meeting the requirement of Risk-based thinking: (1/3)

In order to implement risk-based thinking, the standards organization recommends using the "PDCA" rule circle [Plan-Do-Check-Act].

- Risk-based thinking is deep-seated in the standard's clause 6 "Planning".

The illustration shows the individual ISO 9001:2015 clause titles related to the PDCA context.

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Recommendations of the ISO for meeting the requirement of Risk-based thinking : (2/3)

- Identify what your risks are – it depends on context
- Use risk-based thinking to prioritize the way you manage your processes
- Analyze and prioritize your risks
  - *What is acceptable, what is unacceptable?*
  - *What advantages or disadvantages has one process over another?*
- Plan actions to address the risks
  - *How can I aviod, eliminate or mitigate risks?*
- Implement the plan – take action
- Check the effectiveness of the action – does it work?
- Learn from experience – improve

„Successful organizations intuitively apply risk-based thinking"

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Recommendations of the ISO for meeting the requirement of Risk-based thinking : (3/3)

Open questions:

1. Do you find the aforementioned indications precise enough to start properly handling organizational risk now?
2. Will "risk-based thinking" lead to the recognition of uncertainties and the reduction of their negative influences without structured, comprehensible procedures?
3. Is just risk-based thinking enough to succeed?

Whether only the thinking by the Think-Slim concept has ever really slenderized someone, that still needs to be confirmed first.

✓ **To recognize risk and improve it, don't just think – act !!!**

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and the Risk-based approach

„ **Risk** comes from

not knowing what you`re doing.”

Warren Buffett

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ISO 9001:2015 doesn't explain:

What is actually „Risk?"

Organizations are subject to internal and external influences that make it uncertain whether, when and to what extent this organization will achieve its objectives

Risk... is the effect of such uncertainty on the objectives, regardless of the area of influence or circumstances

Risk is the expression of a combination of two factors:
- *the consequences (incl. change in circumstances)*
- *and the associated likelihood of occurrence*

of an event or a threat

Risk Management... is therefore an organization's entire coordinated directing and controlling activities regarding risk

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and the Risk-based approach

How does risk arise?

- In organizations, people work purposefully to fulfill their tasks. They make decisions and take advantage of opportunities. They actively design the future.
- Events based on own or third party decisions and even on force majeure can influence achievement of one's objectives.
- But the future is uncertain in principle - therefore, results can occur contrary to expectations.
- Organizations use a variety of methods to influence the consequences of uncertainties ("risks") on their objectives.
- The increasingly complex, globalized business world requires to recognize and understand risks in a targeted manner in order to cope or at least mitigate them.

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and the Risk-based approach

The Aim of Risk Management:

- ✓ Reduce the effect of uncertainties and threats
- ✓ Improve financial stability
- ✓ Protect corporate ressources
- ✓ Increase reliability of decision making and planning
- ✓ Improve incident management and minimize losses
- ✓ Increase confidence and trust of customers and partners
- ✓ Enhance safety of employees and the environment

➢ *…and thus improve operational effectiveness and efficiency*

Risk Management is a Leadership Task

…as it is to ensure the organization's resilience and survival by aligning objectives and strategies with risks.

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and the Risk-based approach

What's to be done now?

In section "Other Useful Documents" at the end of their reference paper to risk-based thinking the International Standardization Organization has linked the following further reading:

- **ISO 31000:2009 Risk Management - Principles and guidelines**
- **PD ISO/TR 31004:2013 Risk management - Guidance for ISO 31000 implementation**
- **ISO 9001:2015 Risk-based thinking - power point presentation**
- **ISO 31010:2010 Risk Management - Risk assessment techniques**

With this, ISO presents us with a double statement:

1) Risk Management…	is not mandatory for ISO 9001:2015 certified organizations
2) BUT(!)…	The ISO 31000 series is ISO's preferred reference as soon as a formal concept of risk is seen recommendable for an organization.

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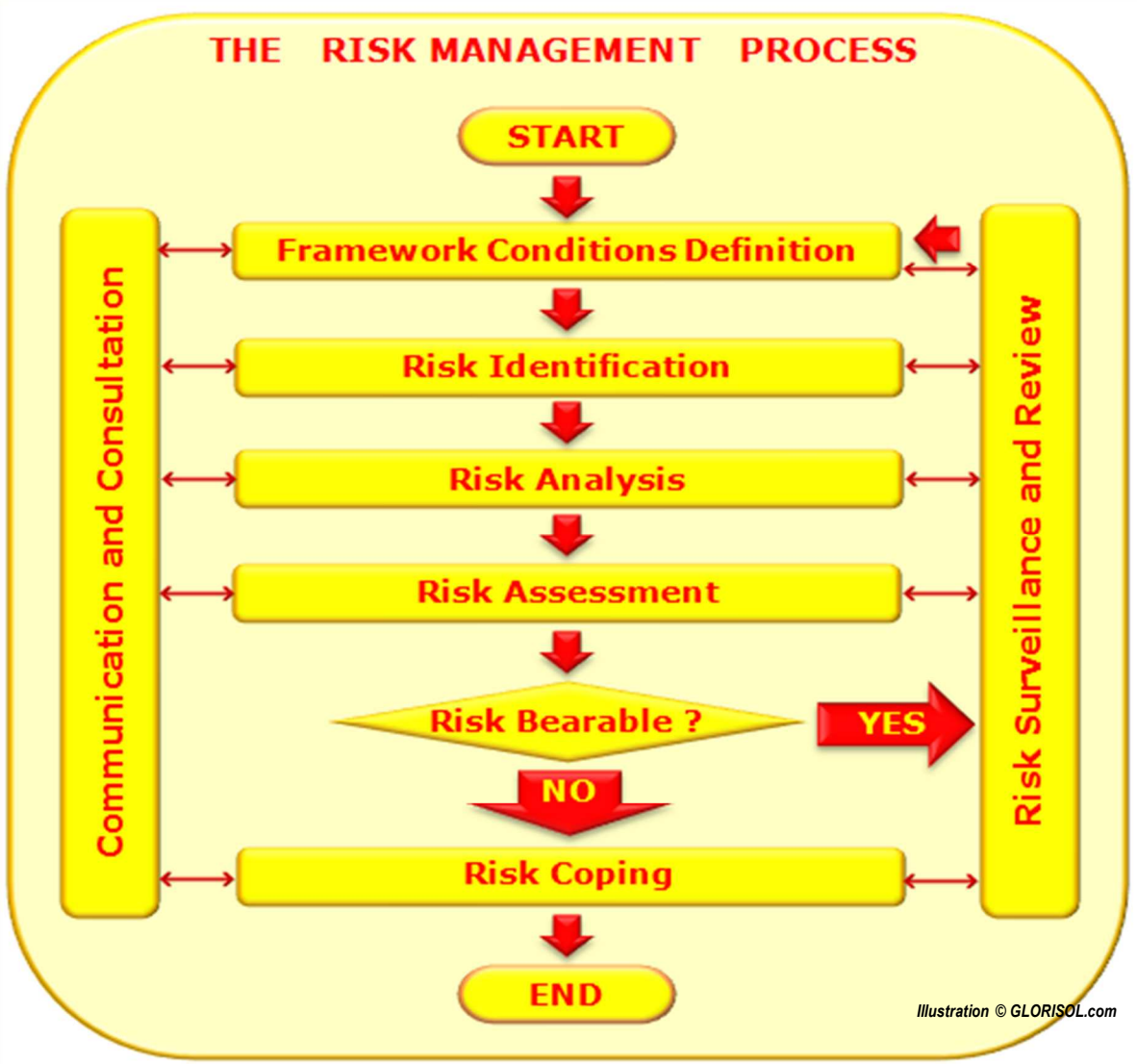
and the Risk-based approach

Risk Management
according to
ISO 31000
is convincing
through sructure:



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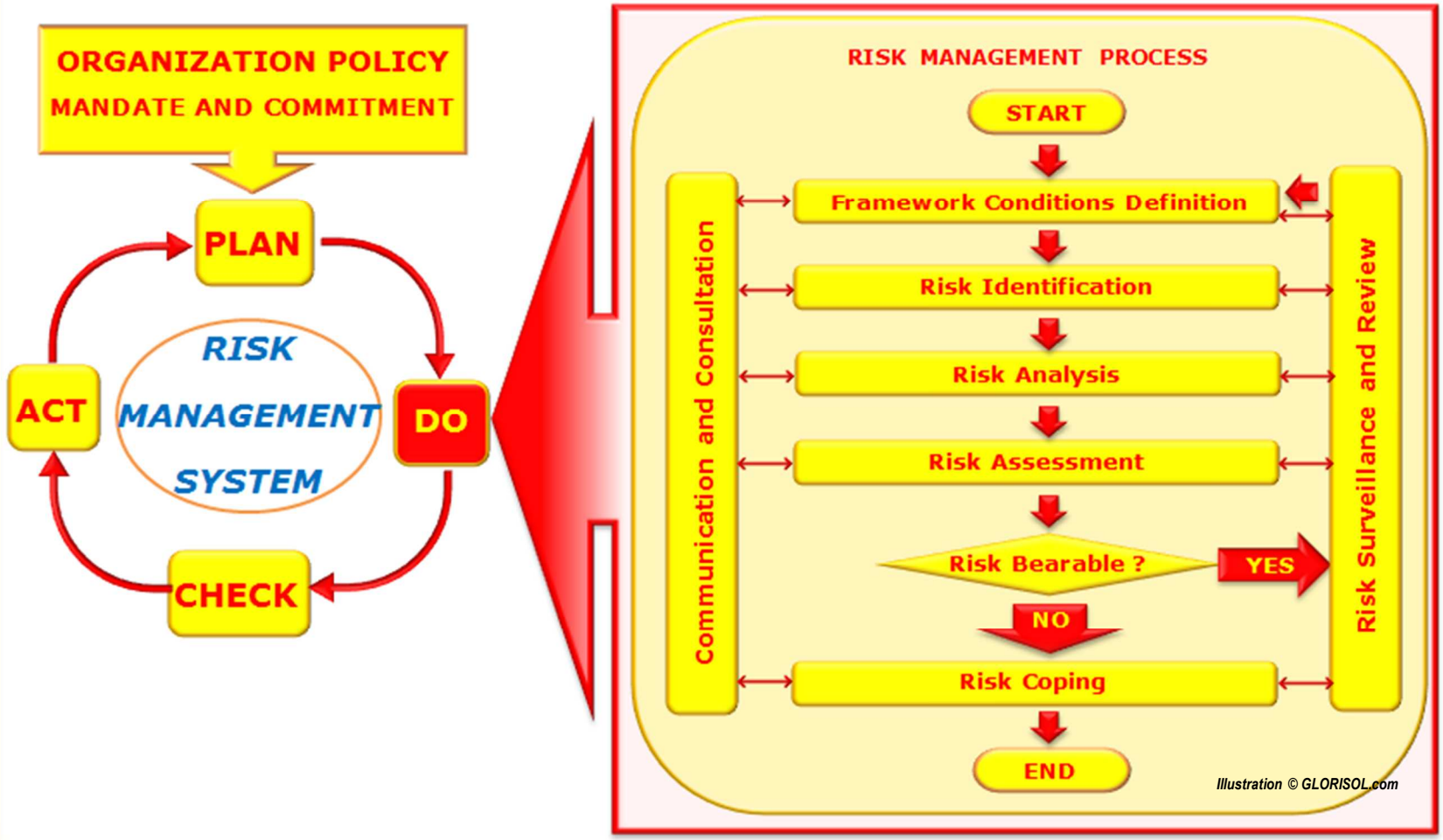
and the Risk-based approach

ISO 31000 is leading: from Risk Management Process
…to the Risk Management System



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and the Risk-based approach

Conclusions: (1/2)

- ISO 9001:2015 has deep-seated risk-based thinking in the "planning" sector of the PDCA cycle. It requires, however, effectiveness of risk-based thinking integrally throughout the entire scope of the quality management system.

- ISO 9001:2015 allows to use an independent method for the implementation of risk-based thinking. But with the user risks of getting tangled up in the topic and, the unavailability of generally accepted, standardized reference points in case of inquiries or issues.

Note: ***Applying the risk-based approach in the continuous improvement context will, as an additional perspective, provide a more complete understanding of the organization's situation***

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and the Risk-based approach

Conclusions: (2/2)

ISO 31000 is an optional tool proposed by ISO that

- offers ISO-recognized, internationally accepted, standardized structures
- provides detailed guidelines for the implementation
- is future-proof through continuing development of the standard
- contains clear terms and a variety of useful explanations
- involves human and cultural factors
- and ISO 31000 systematically analyzes the organization from multiple views, while ISO 9001:2015 considers the organization purely process-oriented (only hierarchically top-down)

ISO 31000 contains the necessary methods and procedures one needs for a appropriate handling of risks according to ISO 9001

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and the Risk-based approach

Next steps

- You want more information about risk-based thinking, risk analysis and risk management?
- You need support in implementing risk management, risk assessment and maintaining the effectiveness of your risk management?

Get in touch – we take care for your topics

GLORISOL® can help your organization to obtain practical advantages in return for the ISO requirement to think risk-based; assess and process risks in plausible ways; build tailored risk management closely along the organization's operational core structures; and grow strong customer confidence arguments that your organization is in control of its risks - a partner of choice.

> *"Improving an organization's Resilience and Efficiency through diligent handling of Chances and Threats - simply call it Risk Management.*

VIELEN DANK!

感谢您的关注！

THANK YOU VERY MUCH FOR YOUR ATTENTION!

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