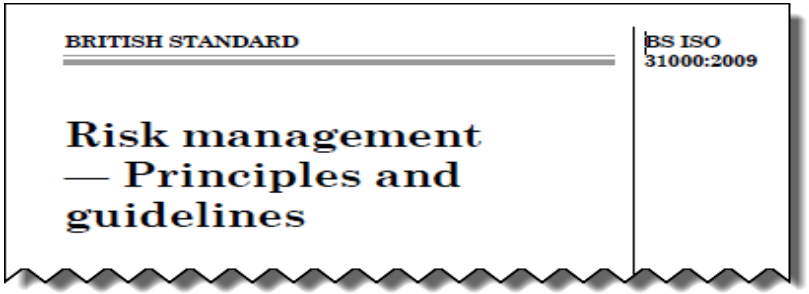
ASQ - Risk

BSI Group Americas

By Royal Charter

ISO Standards for Risk Management, Quality and the HLS



PD ISO/TR 31004:2013

BSI Standards Publication

Risk management – Guidance for the Implementation of ISO 31000

ISO 9001:2015

BSI Standards Publication

Quality Management Systems - Requirements

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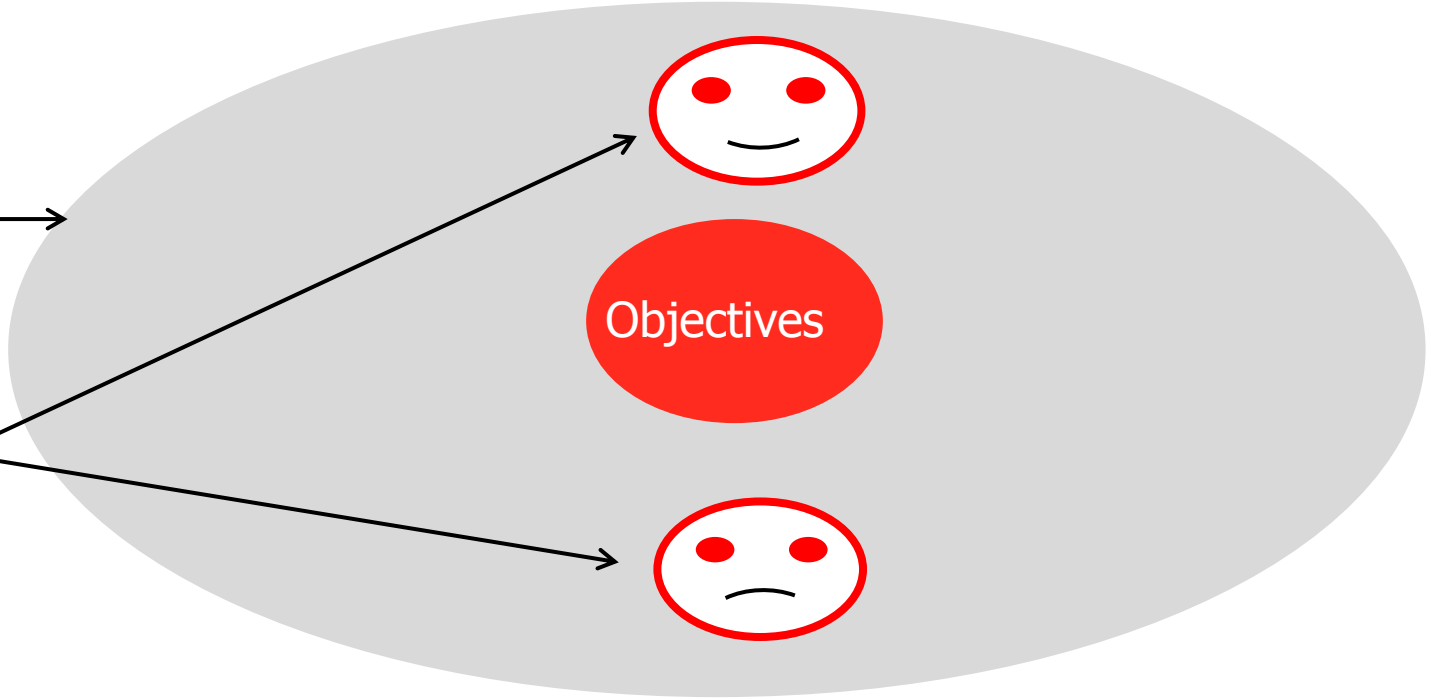
Key concepts, terms and definitions: ISO 31000 Section 2

Risk

Uncertainty in (meeting) objectives

Risk is the effect of this uncertainty in (meeting) objectives: this may be good or bad, significant or insignificant



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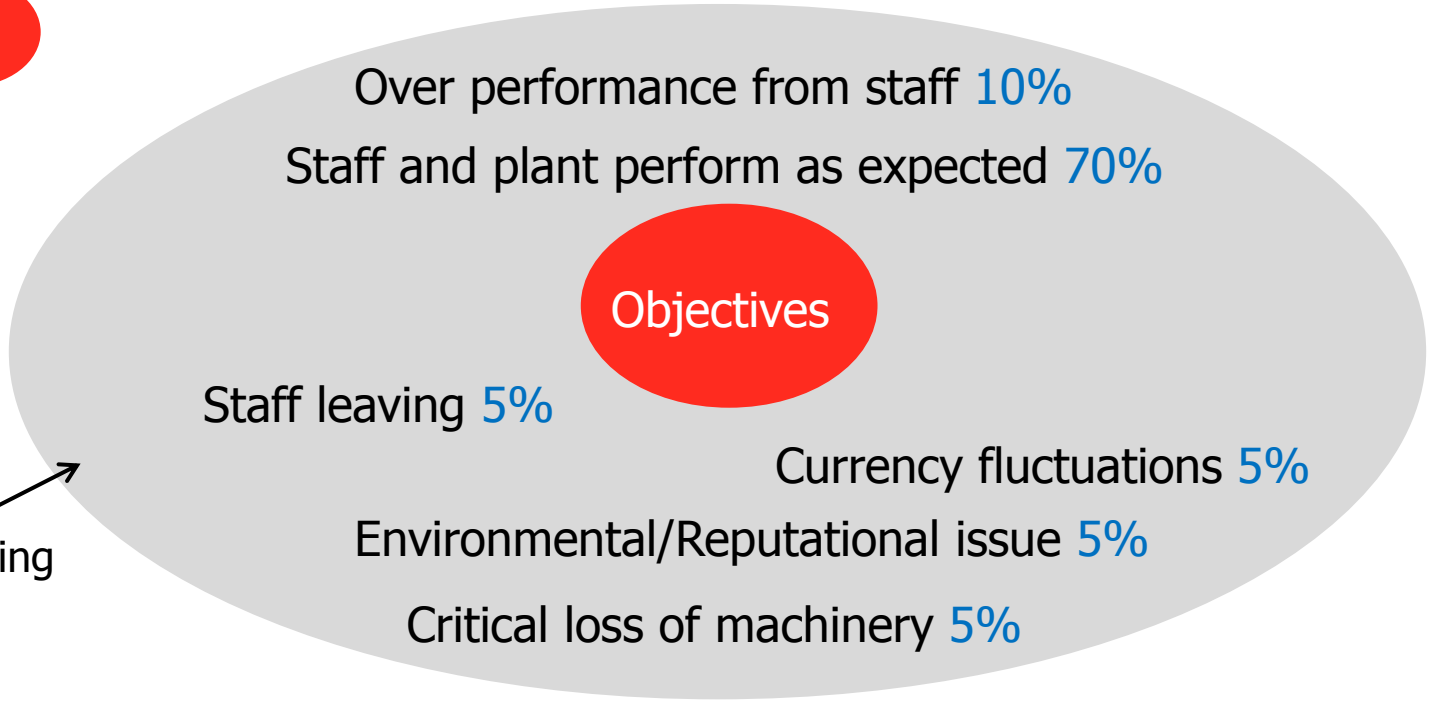
Risk dimensions: PESTLE

Risk can manifest in many different ways. PESTLE is a useful reminder of where to look for risk

Key concepts, terms and definitions: ISO 31000

Likelihood

Likelihood is the chance of something happening (meeting objectives in this case)



Uncertainty in meeting objectives – which contains a whole range of likelihoods

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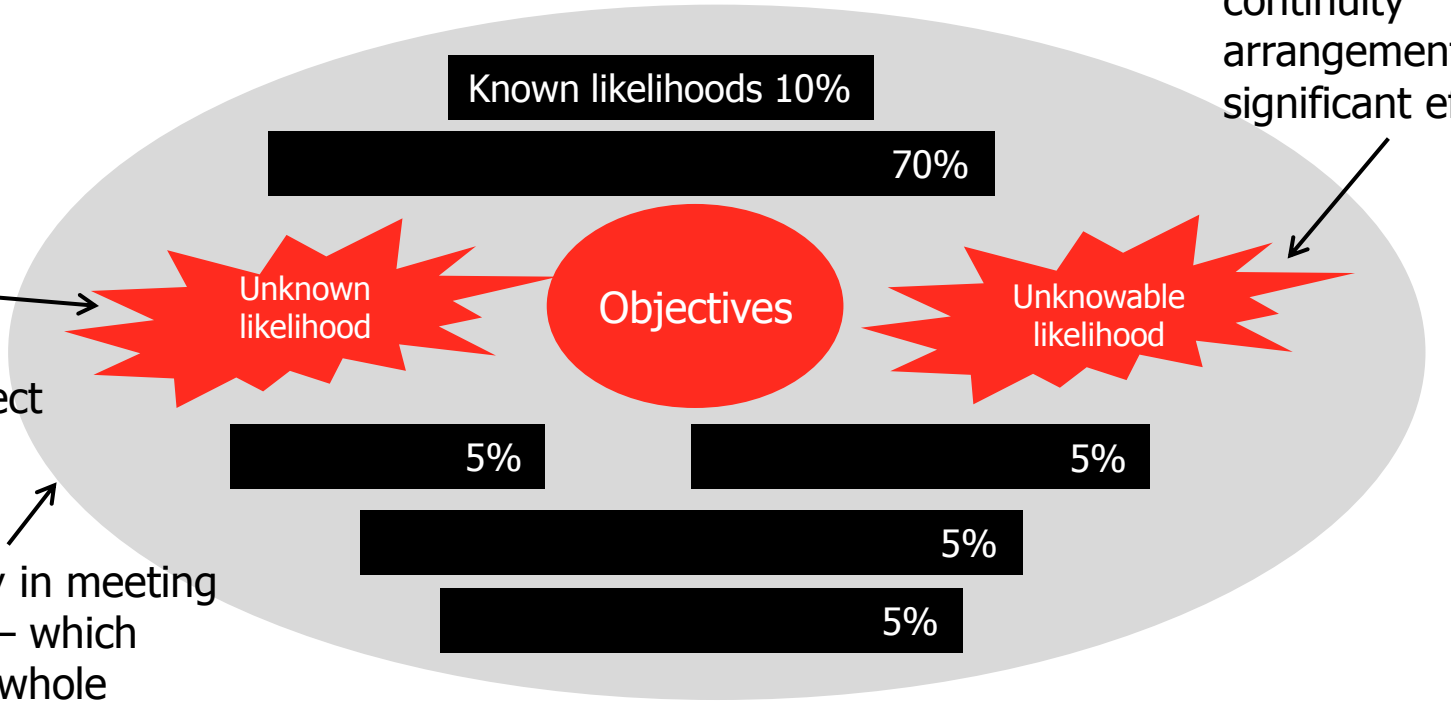
Uncertainty



Make contingency/ continuity arrangements if significant effect

Determine likelihood if significant effect

Uncertainty in meeting objectives – which contains a whole range of likelihoods

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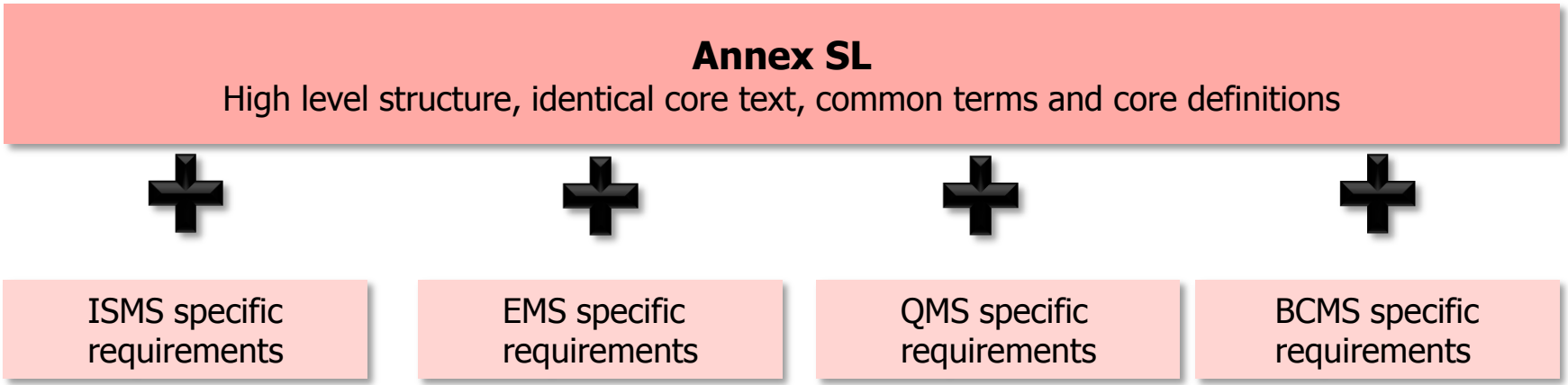
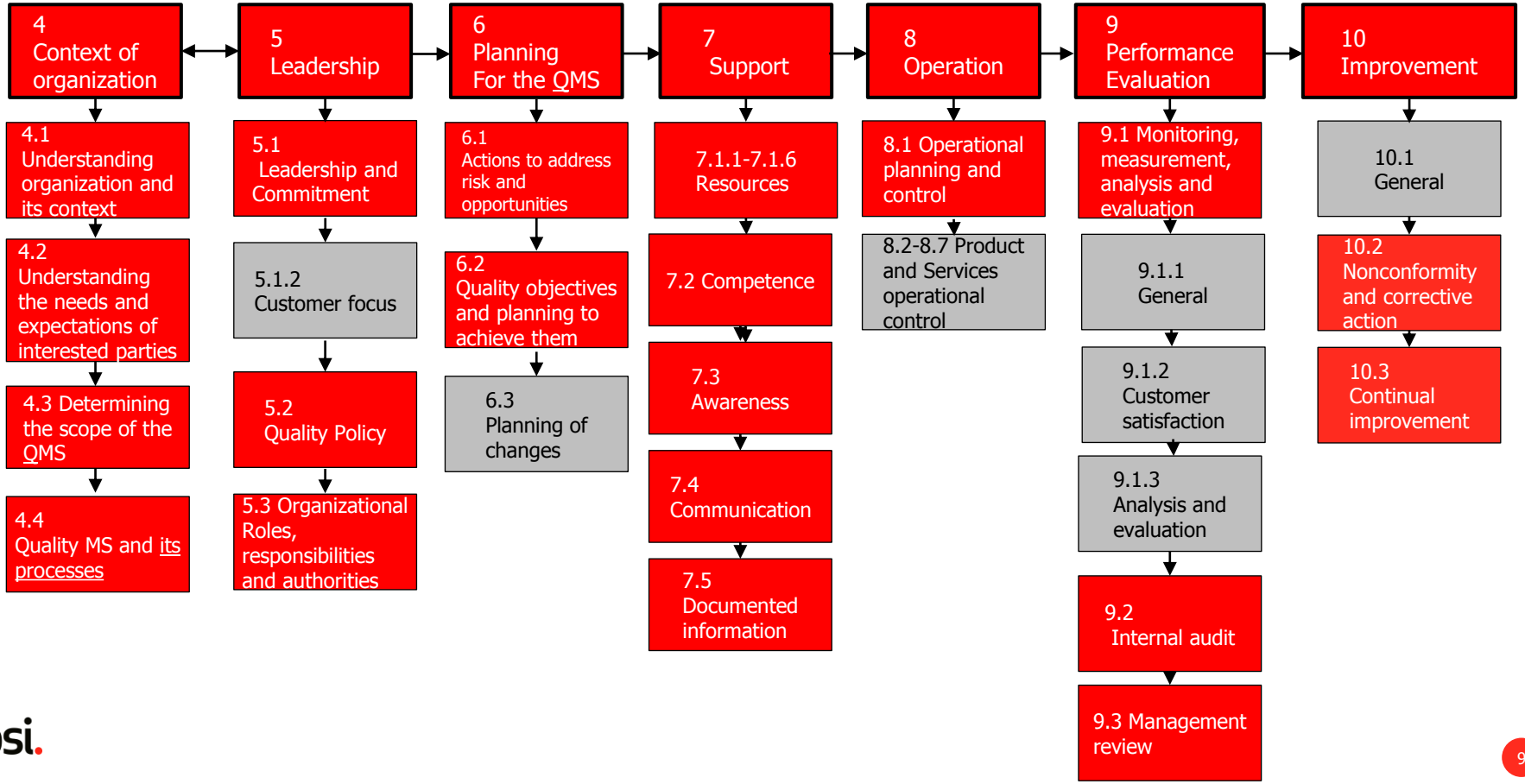
Section 1: Risk Based Thinking

ANNEX SL (HLS)

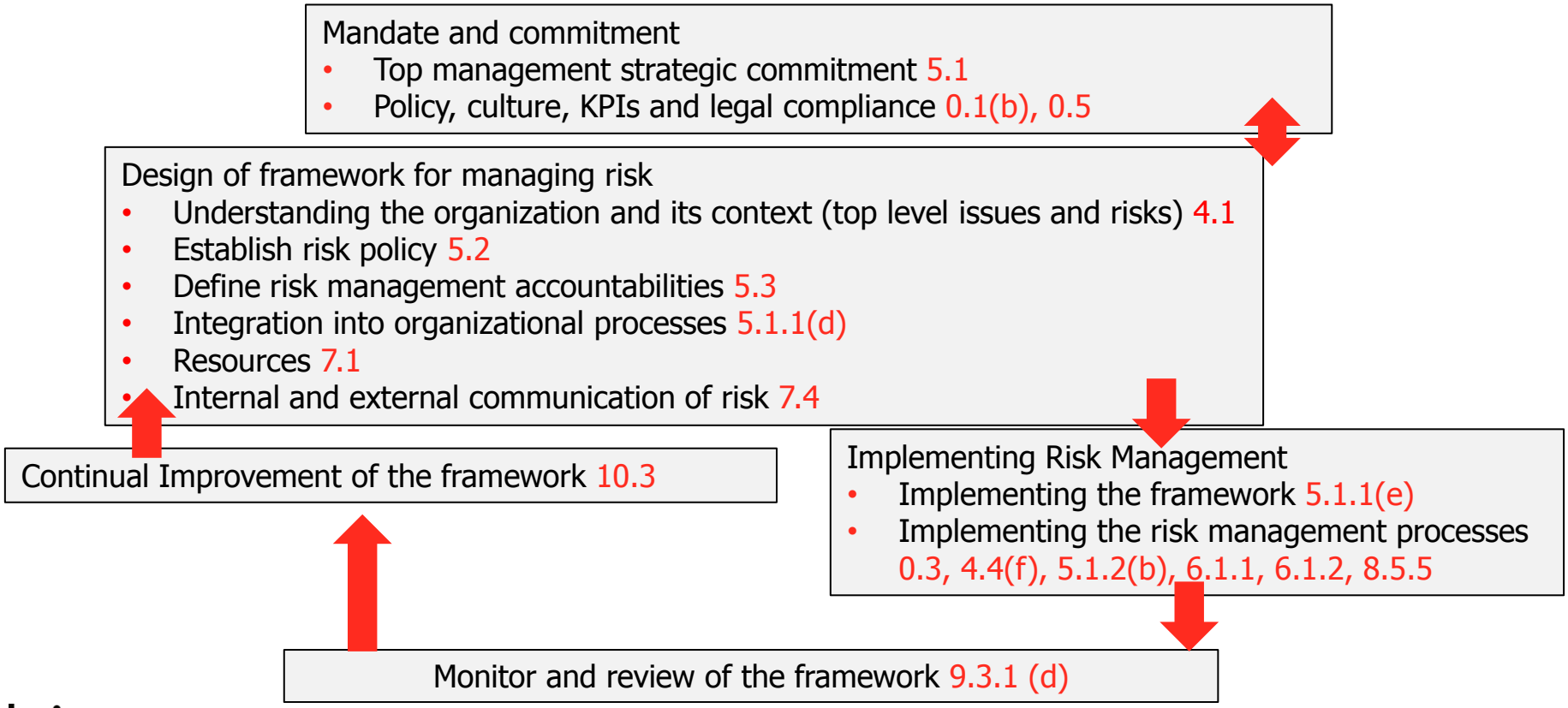
- Annex SL
  - high level structure,
  - identical core text,
  - common terms and core definitions.



HLS and additional ISO 9001:2015 structure

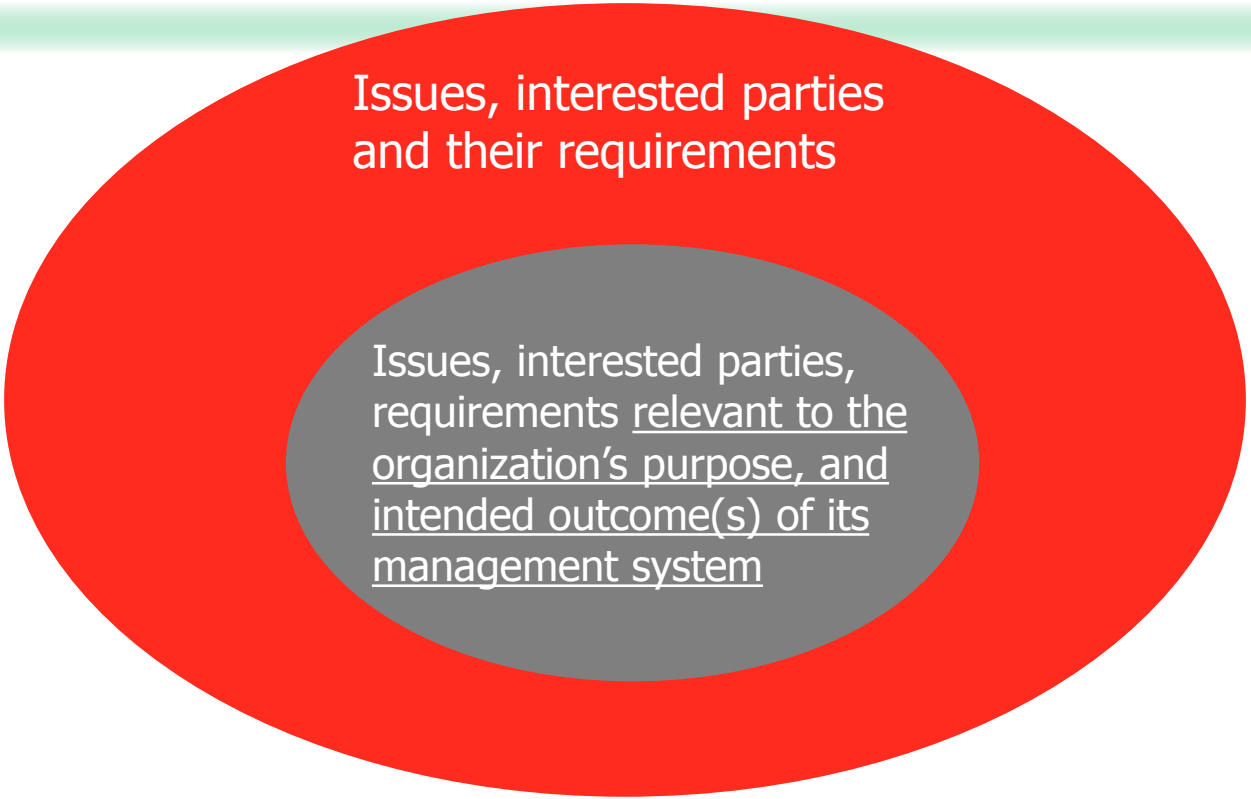


Risk management framework



(Adapted from ISO 31000 © ISO 2009)

Risk-based thinking



ISO 31000:2009 - External context

The external context can include, but is not limited to:

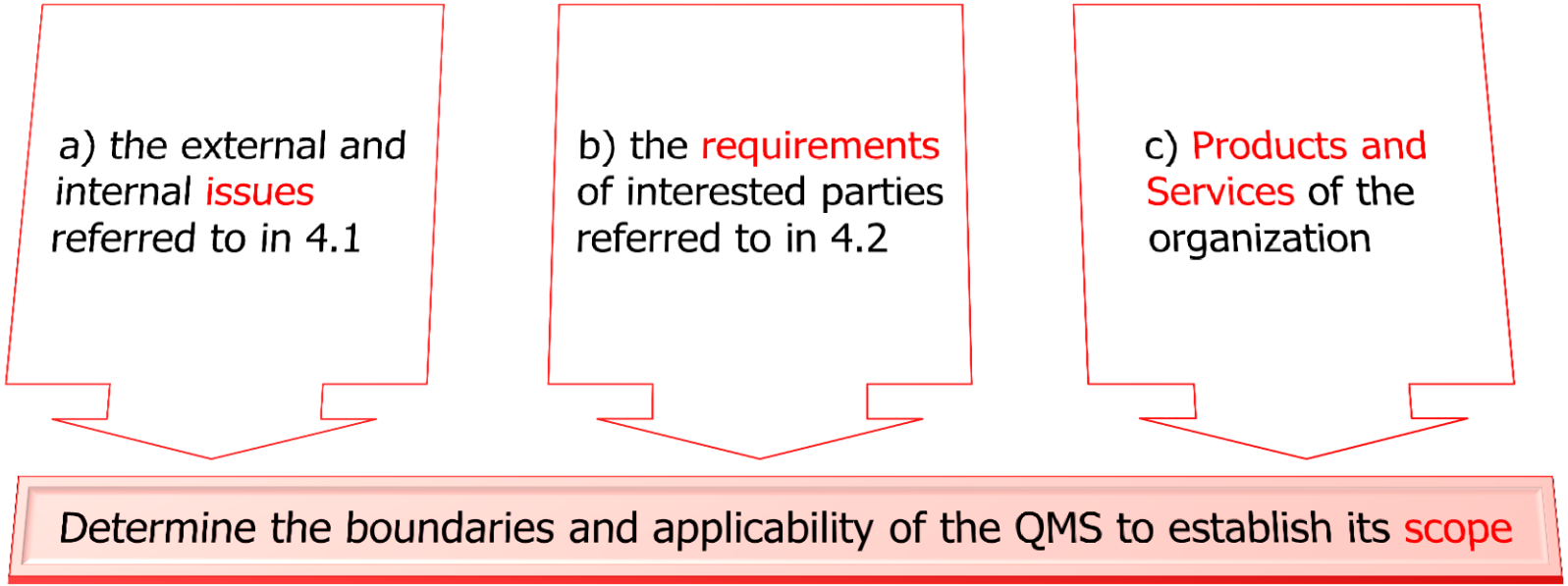
- The social and cultural,
- political,
- legal,
- regulatory,
- financial,
- technological,
- economic,
- natural and competitive environment,
- whether international, national, regional or local;
- Key drivers and trends having impact on the objectives of the organization; and
- Relationships with, perceptions and values of external stakeholders

ISO 31000:2009 - Internal context

Internal context includes, but is not limited to:

- governance, organizational structure, roles and accountabilities;
- policies, objectives, and the strategies that are in place to achieve them;
- capabilities, understood in terms of resources and knowledge (e.g. capital, time, people, processes, systems and technologies);
- the relationships with and perceptions and values of internal stakeholders;
- the organization's culture;
- information systems, information flows and decision making processes (both formal and informal);
- standards, guidelines and models adopted by the organization; and
- form and extent of contractual relationships

4.3 Determining the scope of the QMS



The scope shall be available as documented information

ISO 9001:2015

- There isn't a requirement to:
  - have a risk framework
    - risk is an integrated part of the standard
  - Conduct a risk assessment
  - Document the context of the organization
  - Document the needs and expectations of interested parties, except
    - **4.4.2** To the extent necessary, the organization shall:
    - a) maintain documented information to support the operation of its processes;
    - b) retain documented information to have confidence that the processes are being carried out as planned.

Section 2:
Risk Management

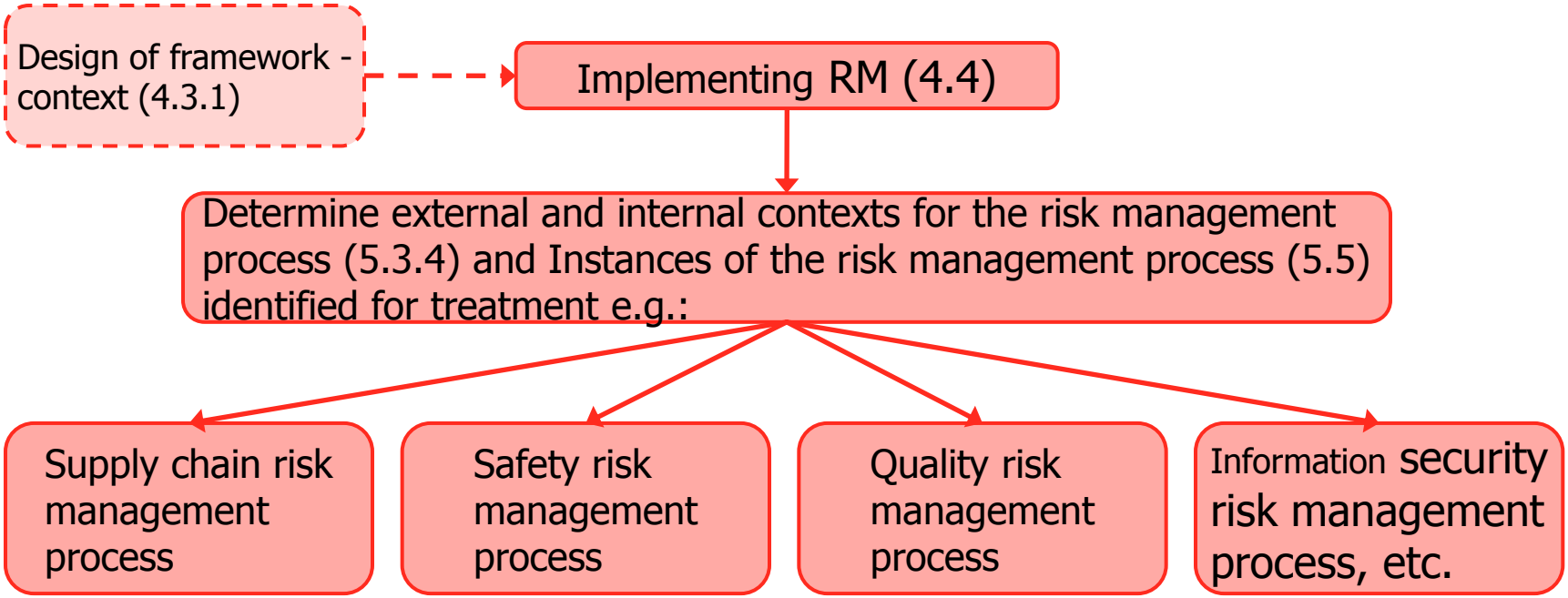
What is Risk Management?

- Risk Management (RM) is a structured approach to managing uncertainty.
- Risk Analysis is the science of risks, their probability and evaluation
  - ISO 31010 contains 31 Risk Assessment Tools;

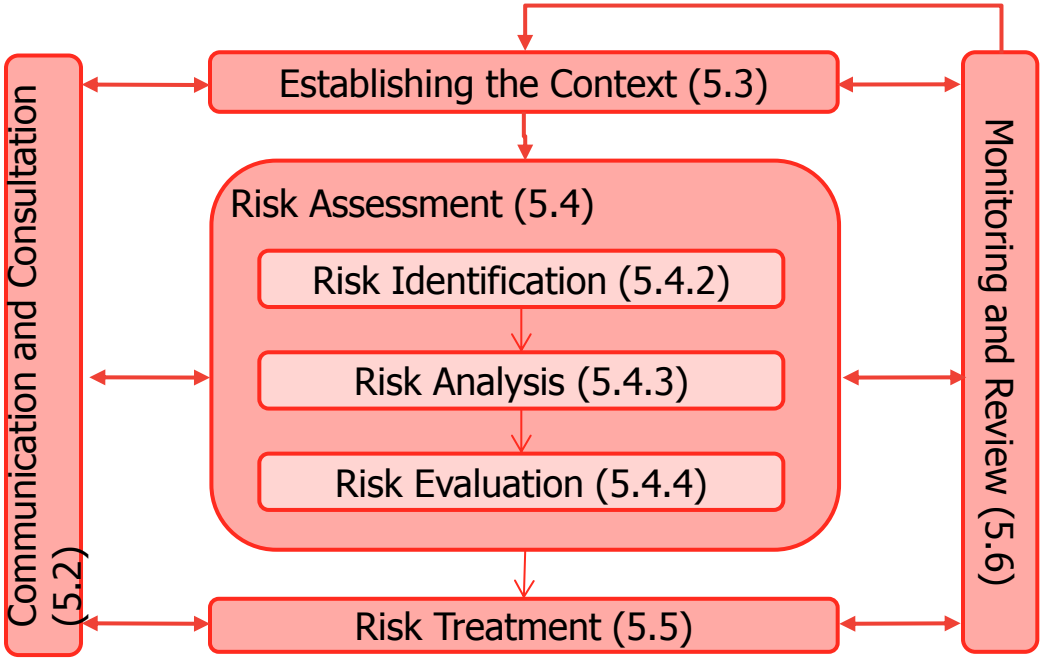
Some Risk Treatment Options

- Avoid the risk by deciding not to start or continue with the activity that gives rise to the risk
- Take or increase the risk in order to pursue an opportunity
- Remove the risk source
- Change the likelihood
- Change the consequences
- Share the risk with another party or parties (including contracts and risk financing)
- Retain the risk by informed decision

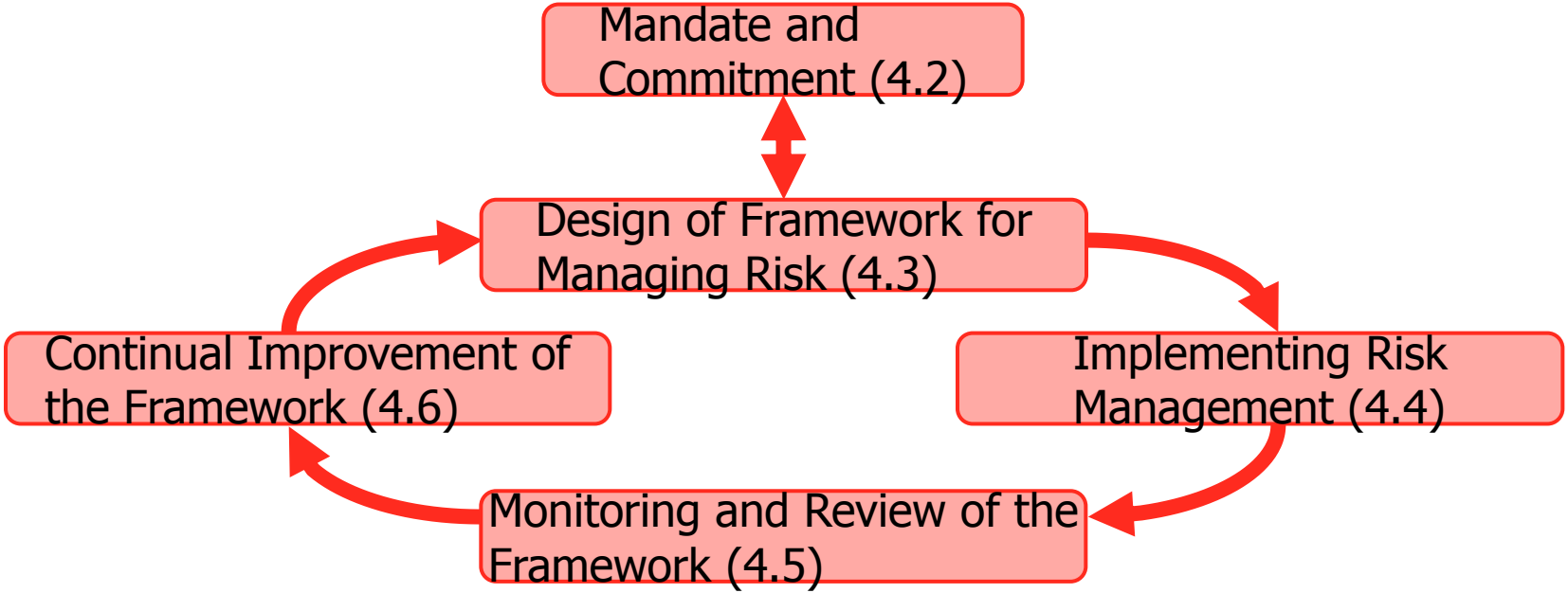
Links Between Framework and Process



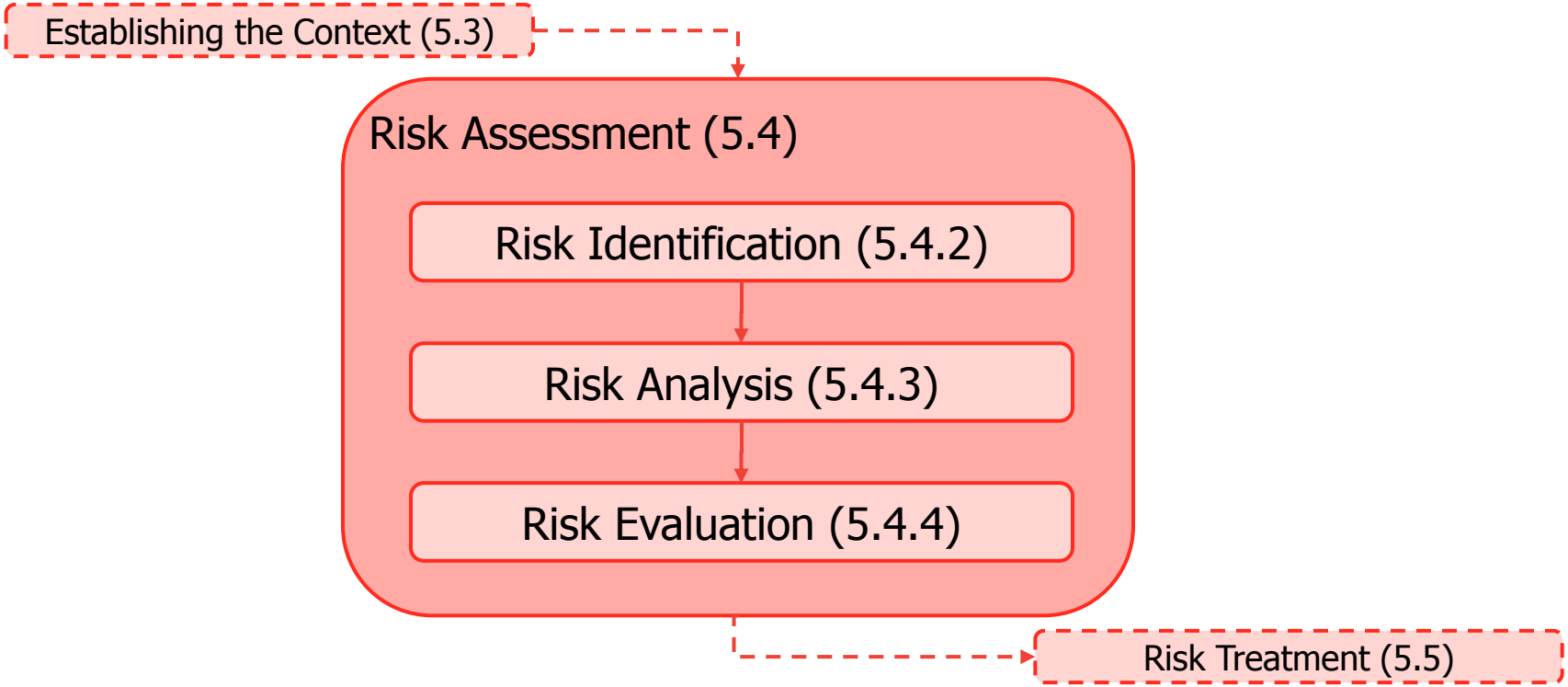
Process, Clause 5



Risk Management Framework:
Monitoring and Review of the Framework



Risk Assessment



Risk Assessment

- A first step in this process is to determine the tools that may be needed:
  - To help and to implement risk management in practice
  - To ensure the organization's risk management framework is aligned with the overall management system and the objectives
  - To ensure it is in keeping with the organization's nature, scale, complexity and culture
  - Assist in the development and risk management knowledge and expertise within the organization

Risk Identification

- The aim should be to produce a set of well-defined risks
- It should include all risks
  - Including those not necessarily under the control of the organization
  - But not necessarily consider every possible sequence of cause and effect
- It should be approached methodically and thoroughly

Risk Analysis

- The way consequences and likelihood are expressed, and how they are combined to determine a level of risk, should reflect the:
  - Type of risk
  - Information available
  - Purpose for which the risk assessment output is to be used
- Should all be consistent with the risk criteria
- Consider the interdependence of different risks and their sources

Risk Analysis (cont.)

- Should enable balancing of one risk against another as part of the risk management decision making process
- The aim is to try and understand the source of the risk and the causes
- Where there are existing controls in place, it can be useful to analyze the risk with and without the control in place and to determine whether the control is robust enough

Risk Evaluation

- Involves comparing the level of risk found during the analysis process using defined risk criteria
- Is used to assist in decision making based on the outcomes of risk analysis…
  - About which risks need treatment
  - The priority for treatment implementation
- Decisions should take account of the wider context of the risk

Risk Treatment

- Cost/benefit analysis of treatment(s)
- Select and implement one or more options for modifying risks
- There can be one or more (in combination or priority order)
- Identify resultant and/or residual risks from treatment
- Document the risk treatment plan
- Assess effectiveness

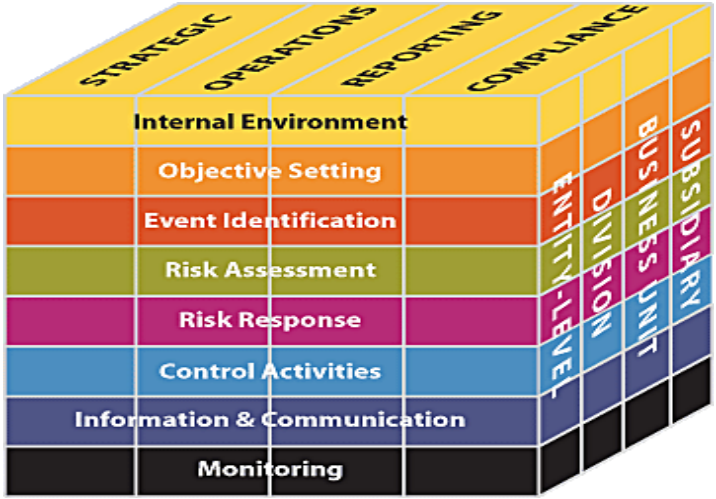
Monitoring and Review

- Uses information from and provides input to Establishing the Context (5.3), Risk Assessment, and Risk Treatment
- Plan for regular checking or surveillance
- Define responsibilities
- Ensure effective and efficient controls
- Evaluate event results, changes, trends, successes and failures
- Identify changes in context, risk criteria, risk
- Report results and incorporate for process improvement

Monitoring and Review

- Use a common approach across processes if the organization already has a management system in place
- Consider useful inputs to and outputs from a review process

COSO ERM Framework



Key Terms and Definitions

Term	Definition
risk	effect of uncertainty on objectives
risk analysis	process to comprehend the nature of risk and to determine the level of risk
risk assessment	overall process of risk identification, risk analysis and risk evaluation
risk evaluation	process of comparing the results of risk analysis with risk criteria to determine whether the risk and/or its magnitude is acceptable or tolerable
risk identification	process of finding, recognizing and describing risks
risk criteria	terms of reference against which the significance of a risk is evaluated
risk management	coordinated activities to direct and control an organization with regard to risk

Questions ?

Thank you for your participation and interest

...making excellence a habit.™