

# **Preparation steps for implementation and auditing against ISO 9001:2015 - Challenges and Opportunities**

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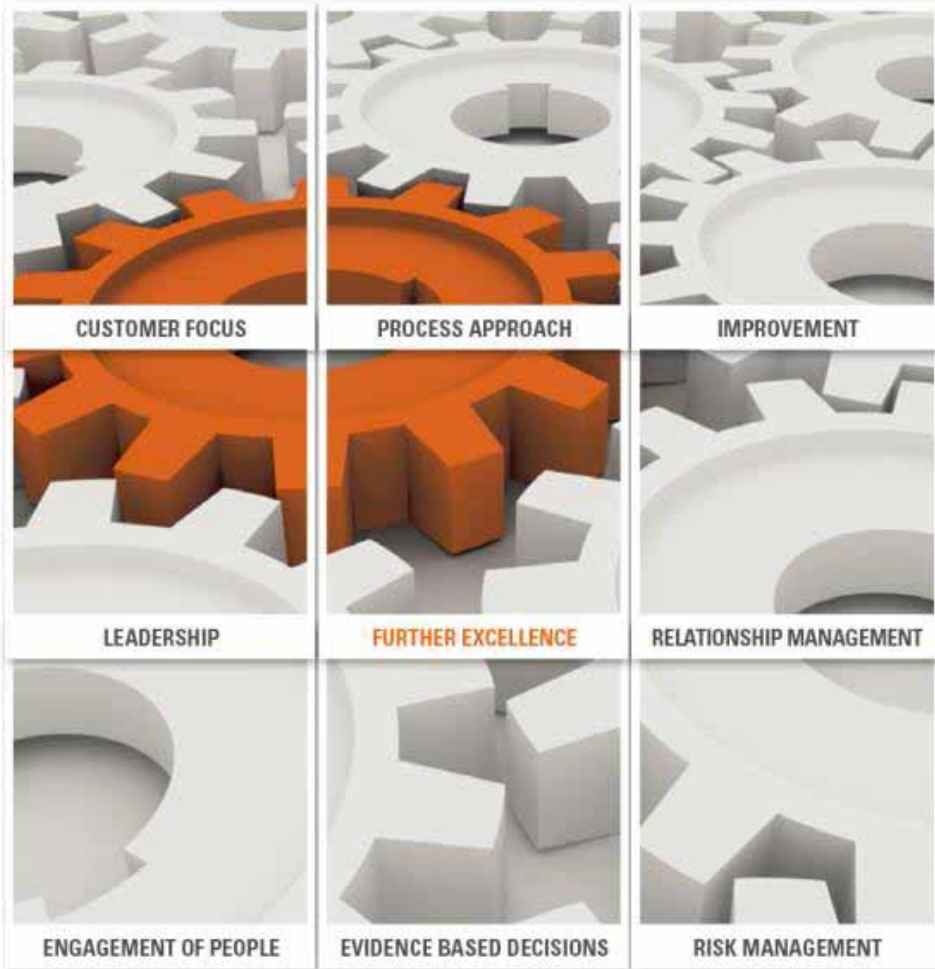
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(ABSTRACT)

All future users of the Quality Management System (QMS) standard are expecting value and significant benefit from implementation of the ISO 9001:2015. Conferences have been organized for quality professionals and training sessions have been completed for certification auditors around the world, well before the issue of the official standard. Already available draft of 9001:2015 positions the new version of the standard as an integral part of an organization's efforts towards the broader aim of sustainable development and promotes it as a tool for improving an organization's overall performance. This is in addition to the fact that the adoption of a QMS is a strategic decision for an organization. The emphasis shall be on leadership, risk-based thinking, process approach and continual improvement.

Recommended preparation for companies may include gap-analysis, trainings, review of current system effectiveness. Some companies still have not fully recognized the benefits of a process oriented QMS, they may consider significant changes to put processes into the focus, instead of procedures. Although risk-based thinking has always been implicit in 9001, it may require professionals and leaders to learn and implement suitable methods for identification of risks and opportunities and address them within the process based QMS. This may be the key issue in most cases, even if the standard itself does not prescribe specific risk management methodologies. During the transition period it is highly important to improve the management systems and do not waste time and efforts with unnecessary changes (e.g. updating document structure).

Certification auditors shall undergo comprehensive training sessions before they are allowed to perform accredited management system audits against the new version of ISO 9001. Focus of auditor trainings are on the ANNEX SL structure, risk-based thinking and analysis of changes of the requirements. Using the right approach, auditors cannot be simply in an inspector role anymore, they shall provide value to the audited organizations.



## PREPARATION STEPS FOR AUDITING **ISO 9001:2015**

ANDRÁS TOHL

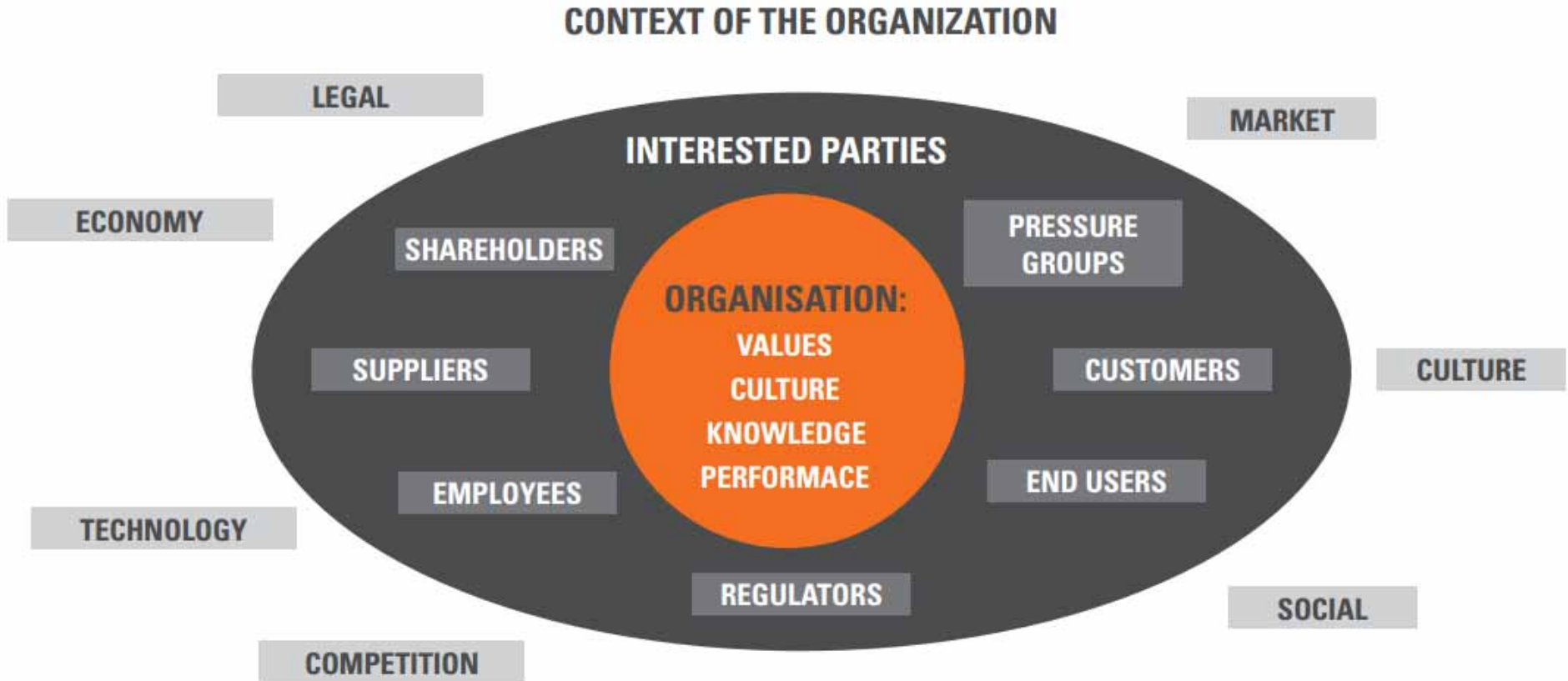
## SGS INTRODUCTION



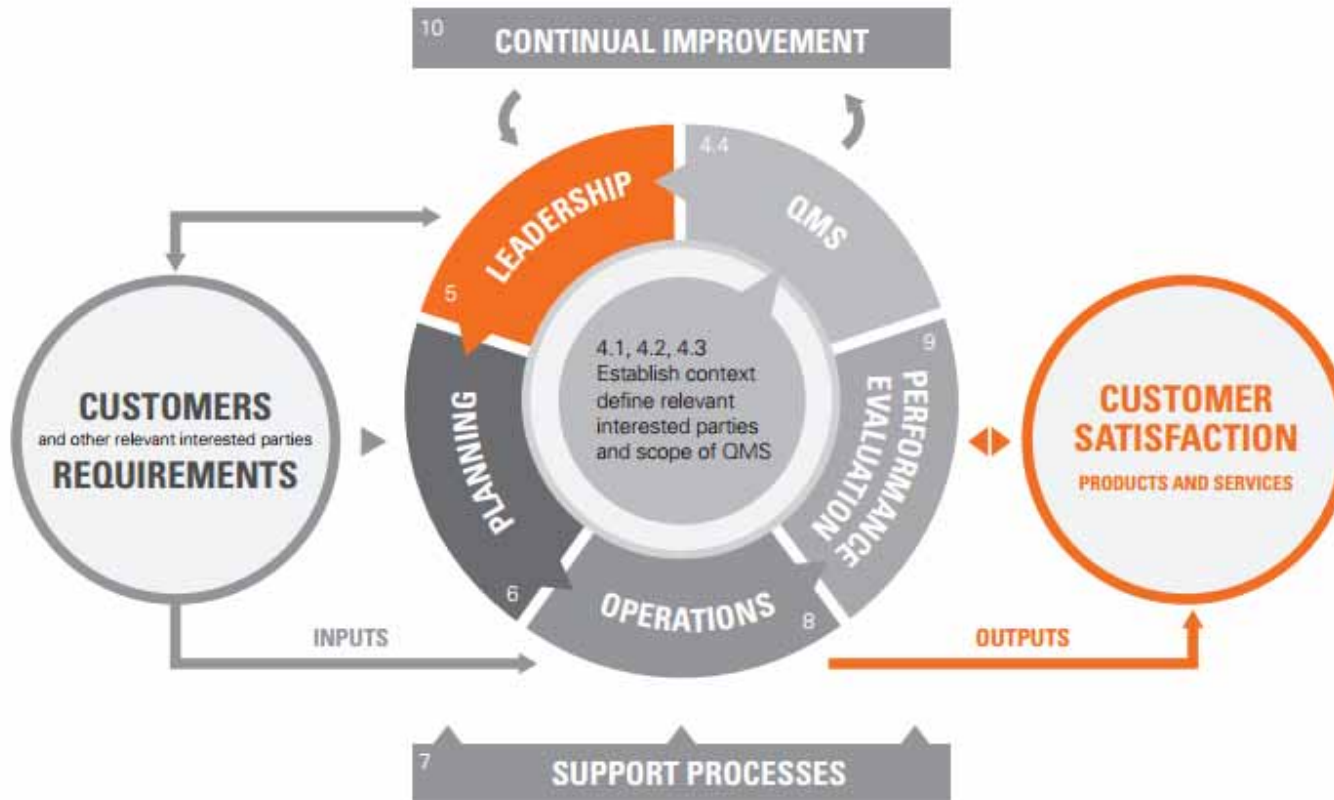
- Founded: **1878**
- Head office: Geneva
- Activities: Inspection, testing and certification
- Organisation: 80.000 employees, 1650 labs, 140 countries
- ISO 9001 certification: the most widely accredited certification body with more than 40 local accreditations worldwide  
IRCA registered lead auditors and training courses



# CORE ELEMENTS: CONTEXT AND INTERESTED PARTIES



## KEY ELEMENTS OF ISO 9001:2015



- Leadership
- Risk-based thinking
- Process approach
- Improvement

## EXPECTED CHANGES TO AUDIT METHODOLOGY



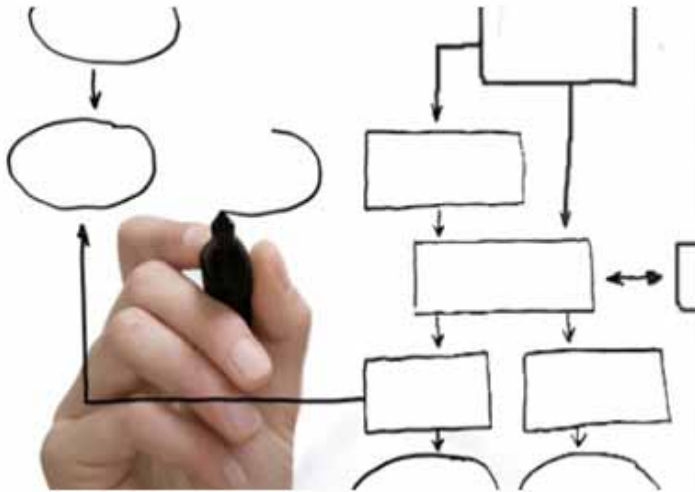
- Adopting the risk-based approach
- Effective involvement of management
- Process approach
  - Forget the clause-by-clause auditing
  - Less focus on documents more on system effectivity
- Support for improvement of QMS
  - Value added auditing
  - Forget the compliance audits





- Prevention always was important part of QMS
- Check how risks and opportunities are indentified
- Basis for planning QMS
- Focus during audit
- Evaluate effectiveness
- Check that management evaluated effectiveness

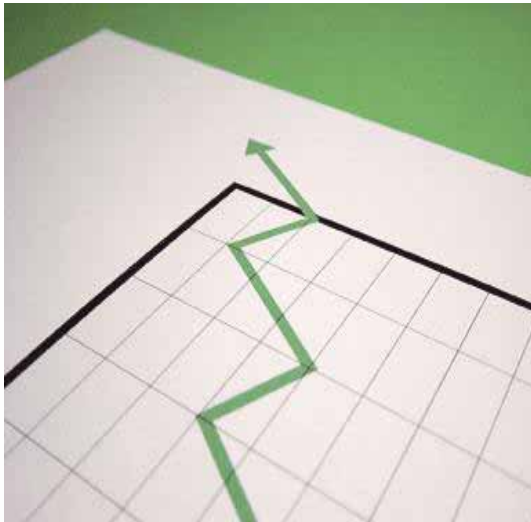




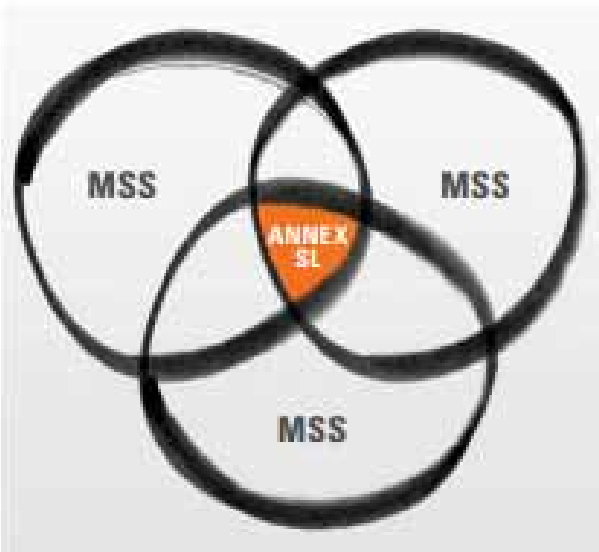
- PDCA
- Do not audit procedures – audit processes
- Not a new requirement: elements of QMS are the processes
- Management system integrated in business
- Auditing business processes instead the clause –by clause approach



- Involvement
- Interviews, presentation
- Not only records
- Not only one responsible
- Evaluate leadership:
  - Setting policy and objectives
  - Promotes process approach
  - Motivate and improve
  - Achievement of expected outcome



- Policy and objectives in accordance with decisions
- Management promotes improvement
- Achievement of objectives
- Measurement of quality performance
- Management reviews:
  - Effectiveness of risk management
  - External and internal aspects of environmental context
  - Strategy
  - Quality performance data, trends and indicators
  - Opportunities for improvement



- ANNEX SL structure
- RISK management
  - Principles and methods
- ISO 9001:2015 requirements
  - Face-to face cascade training
  - Knowledge test
  - Transition Training courses
- Process audit tools
  - New content for stage 1 instead of desk-study
  - Risk based stage 2 process audit
  - Auditing management
- IRCA report on auditing



- Risk-based thinking
  - Audit planning
  - Audit working documents
  - Checking evidence
- Focus on processes...
  - ... and not on documented procedures
- Added value: not only a compliance audit



- Do you have a **documented procedure** for this requirement?
- Is that approved?
- Are the record as evidence?
- How people are trained to use those procedures and records?
- Who is the QA manager who should maintain this?

**ISO CLAUSE OR PROCEDURE BASED – COMPLIANCE AUDIT**



- Did you define the **process**?
- Are there procedures where required?
- What are the **customer needs**?
- How the customer satisfaction is monitored?
- How quality objectives are defined?

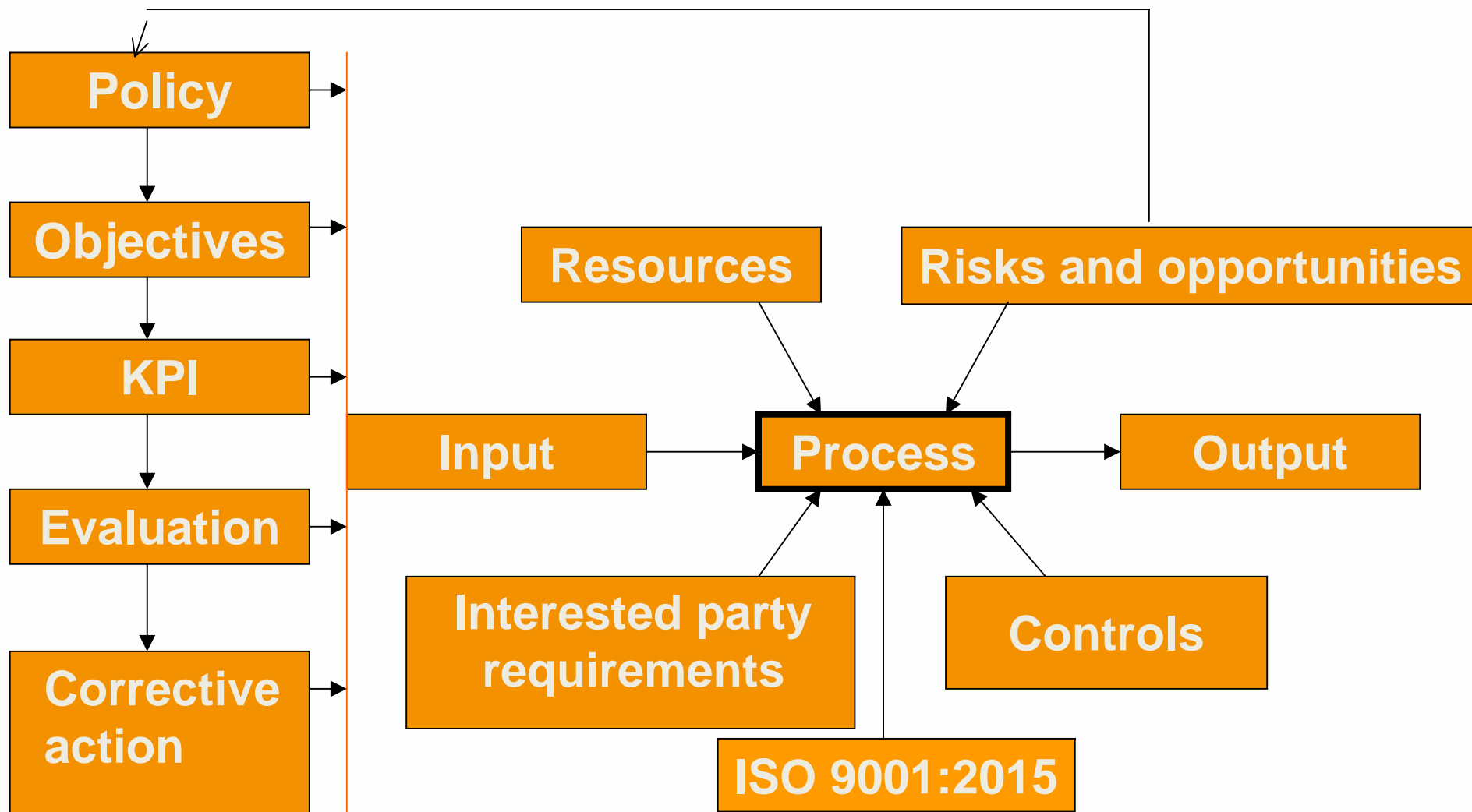
## PROCESS BASED – COMPLIANCE AUDIT





- How are the **risks** identified?
- What are the needs of **interested parties** ?
- Did you define the process to manage?
- How effectivity is evaluated?
- Is customer satisfaction improved?
- How management promotes improvement?

## **RISK BASED**– PROCESS AUDIT





■ **‘Disappearing’ formal approach:**

- Quality Manual
- One single quality manager
- Documented procedures required by the standard itself

■ **Focus:**

- Risks and opportunities
- Process approach
- Management
- Improvement