



# **Integral management system based on ISO 9004:2009 Risks and opportunities on the road towards sustained success**



**III Fórum Internacional da Qualidade  
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**I Q G**

**H E A L T H  
S E R V I C E S  
A C C R E D I T A T I O N**

**Bob Alisic**

***ActinQ***

**consulting, training & auditing in Quality**



# Health Care today and tomorrow

## Issues:

- Cost reduction
- Quality requirements
- Speed
- Security
- Different stakeholders
- Diversity in the market
- Turbulence
- Sustainability
- .....



# Customers and Interested parties?

## Customers / users:

- Patients
- Clients
- Insurance companies
- Government
- .....

## Interested parties:

- Shareholders
- Patient societies
- Employees, specialists
- Insurance companies
- Government
- Suppliers & partners
- Society
- Universities
- .....



# Requirements and expectations?

Interested party (examples):	Requirements & expectations:
<b>Patients</b>	<ul style="list-style-type: none"><li>• <b>Successful treatment</b></li><li>• <b>Security</b></li><li>• <b>One visit and short stay</b></li></ul>
<b>Insurance companies</b>	<ul style="list-style-type: none"><li>• <b>Reliability of information</b></li><li>• <b>Cost reductions, speed</b></li></ul>
<b>Government</b>	<ul style="list-style-type: none"><li>• <b>Impact on the health of the people</b></li><li>• <b>Effective management</b></li><li>• <b>Cost reductions, speed</b></li></ul>
<b>Employees</b>	<ul style="list-style-type: none"><li>• <b>Remuneration, recognition</b></li><li>• <b>Safety at work,</b></li><li>• <b>Opportunities for development</b></li></ul>
<b>Suppliers &amp; partners</b>	<ul style="list-style-type: none"><li>• <b>Mutual benefits and continuity</b></li></ul>
<b>Society</b>	<ul style="list-style-type: none"><li>• <b>Responsible behavior (waste of materials, energy, contribution to prevention)</b></li></ul>



# What is “sustained success”?

**Ability to maintain or develop its performance in the long term:**

- emphasizes the need for a balance between economic-financial interests of an organization and those of the social and ecological environment;
- relates to the stakeholders of an organization (such as customers, shareholders, employees, partners and society).



## What is “success” in daily practice?

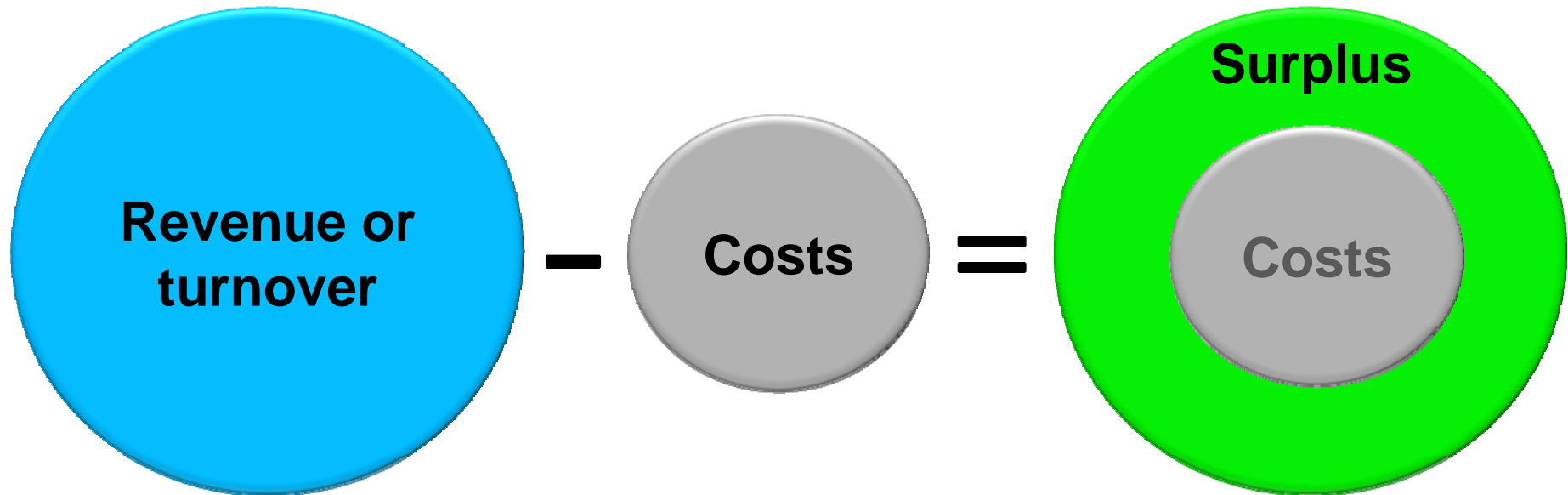
“An organization achieving sustained success is able to work with all relevant interested parties and to satisfy their needs and expectations.”

Nice, long sentence, but what does it really mean?  
What should I do as a manager?

**.....You should divide your “cake” in a balanced way between all relevant interested parties..... ???**



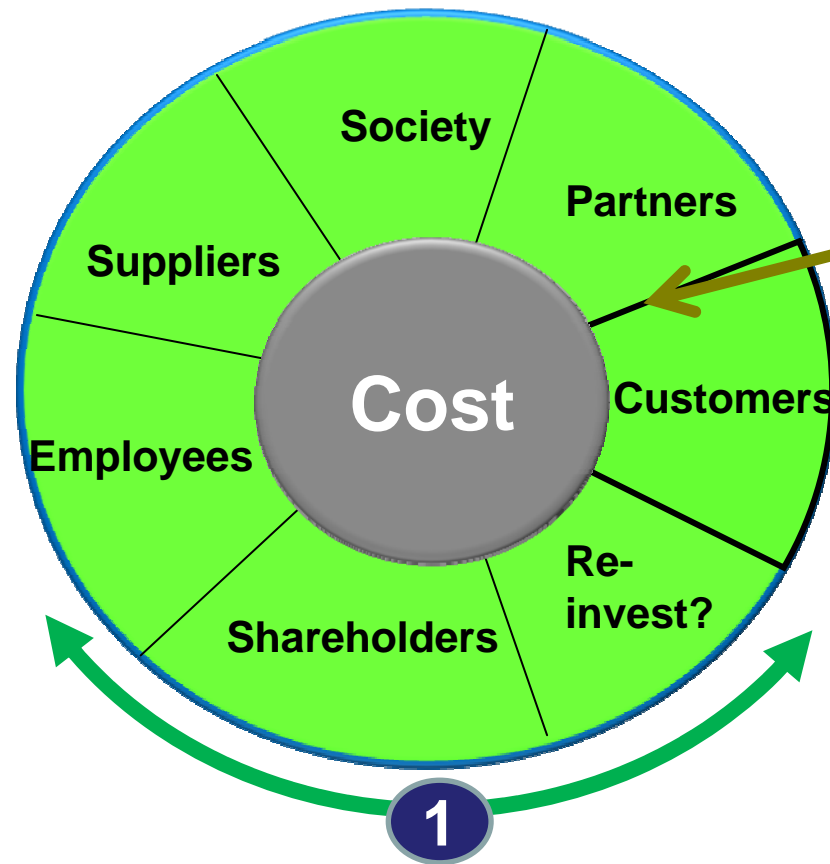
## What is “success” in daily practice?



**Green part: Surplus,  
money that could be  
reinvested, or “given”  
to one or more  
interested parties.**



# The cake - How to divide it between the interested parties?



But also: Time and attention!

**Surplus**  
(profit not allocated yet)

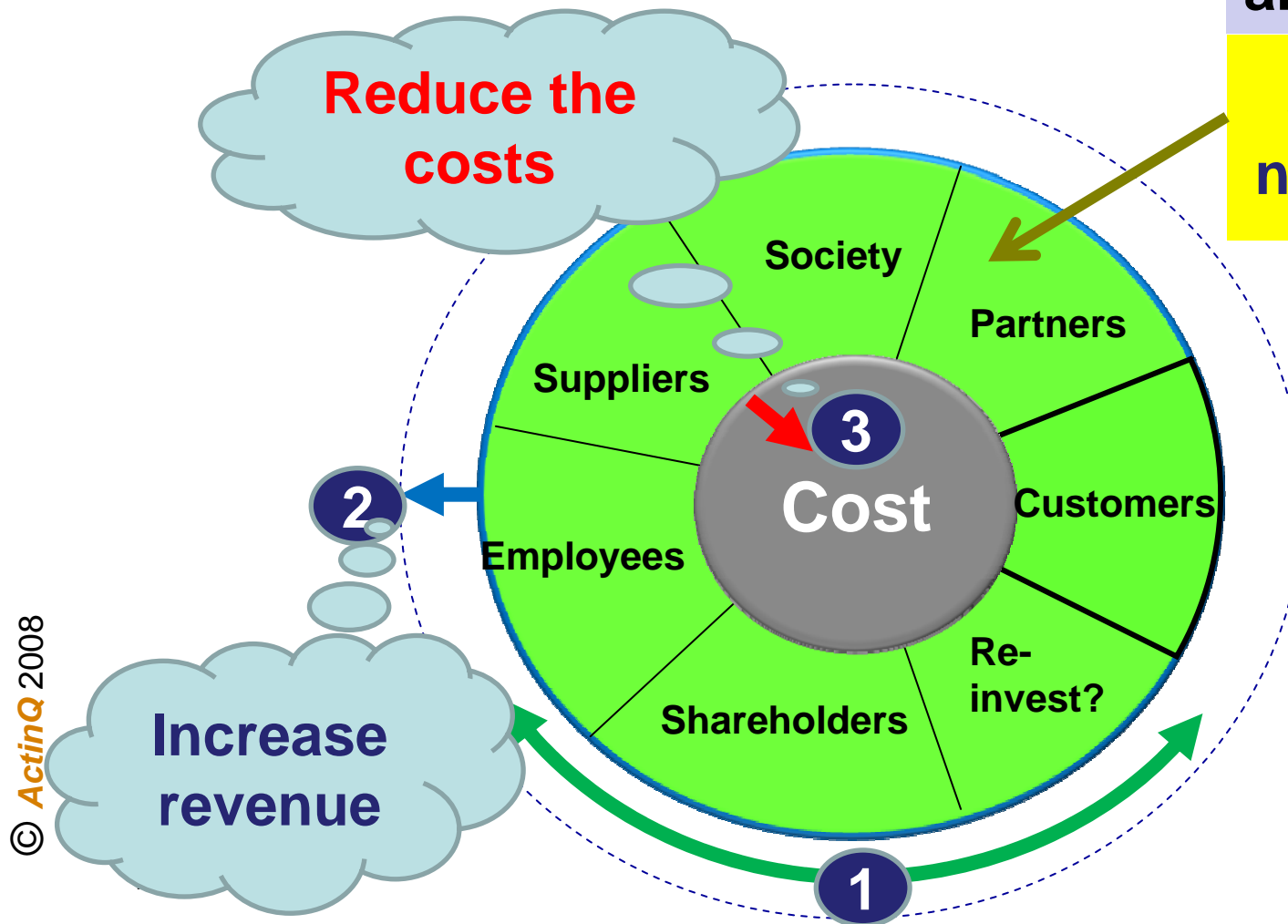
**Balancing act**



# The cake – but also, how to make it bigger?

But also: Time  
and attention!

Surplus (profit  
not allocated yet)



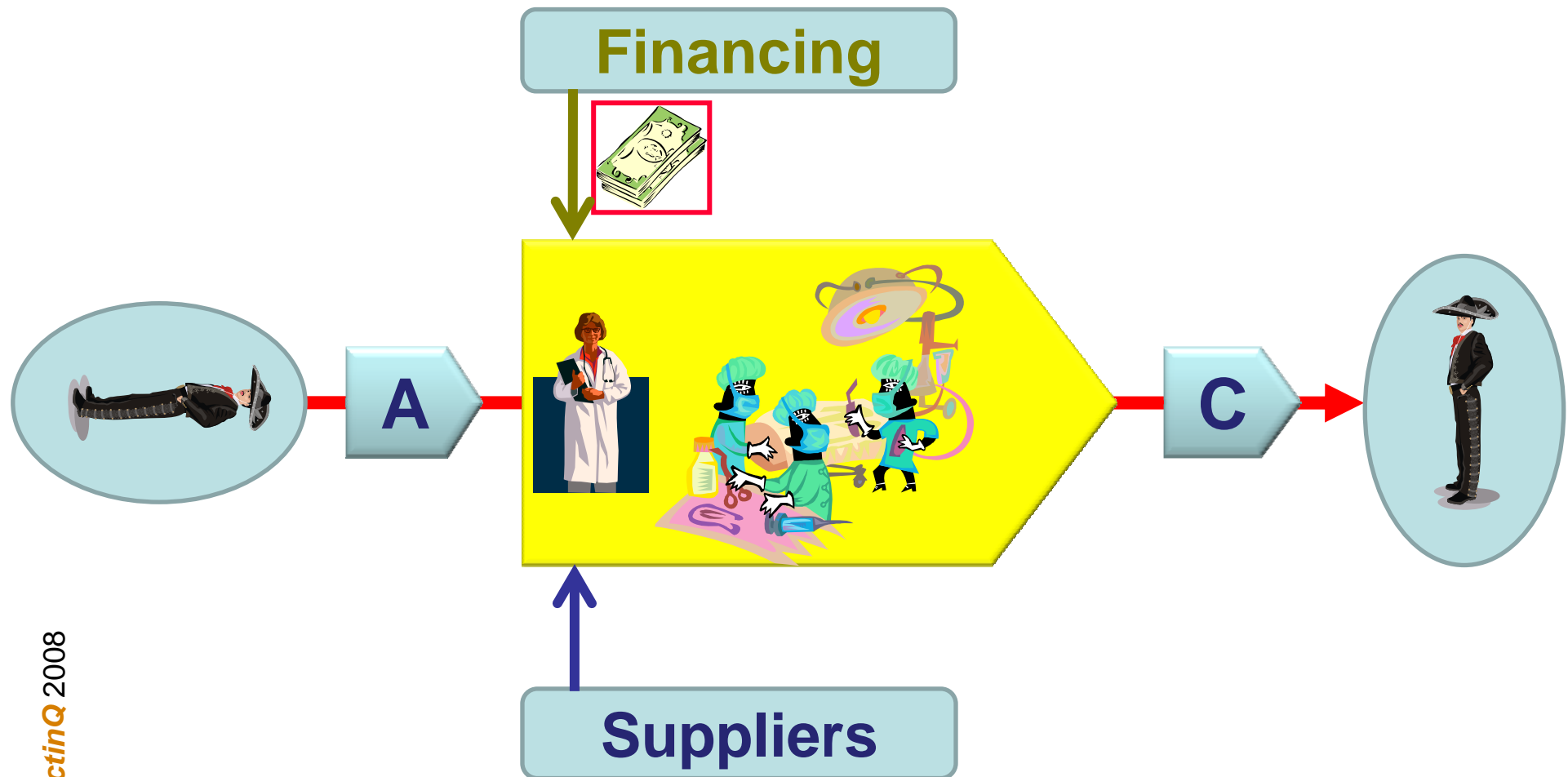


# What are the “**essentials**” of a successful organization?

- ✓ Continuously scanning of own external environment.
- ✓ Continuously scanning of own internal environment.  
Where are we good in, and where are we not (yet)?  
Look in the mirror!
- ✓ Making choices what to be for which of the stakeholders.  
Looking for the balance in satisfying the different stakeholders.
- ✓ Developing and implementing the strategies to align the own capabilities with the new, coming needs.
- ✓ Monitoring (looking into the mirror) and developing of own capabilities for learning and implementation of changes.  
Building agility (speed, innovation, flexibility).



## Basic chain of the processes:





# What are the key issues and challenges?

## Different stakeholders & their expectations?





## Approaches and tools available

- Process mgt.
- Basic Quality Mgt. system based on ISO 9001
- Extended Mgt. system based on ISO 9004
- Environmental Mgt. system based on ISO 14001
- Six Sigma & Lean
- Just In Time
- Agility
- Chain mgt. & partnership
- Management of change
- EFQM, MB, FUNDIBEQ Award models
- and more ..... but!!!



# What approaches and where?

Issue / challenge:	Approach / tool:
Quality requirements	<ul style="list-style-type: none"> <li>• Process management</li> <li>• Quality Mgt System (ISO 9001)</li> <li>• Six Sigma</li> </ul>
Cost reduction	<ul style="list-style-type: none"> <li>• Extended QMS (ISO 9004)</li> <li>• Lean, Six Sigma</li> </ul>
Speed	<ul style="list-style-type: none"> <li>• Extended QMS (ISO 9004)</li> <li>• Lean, Agility, Just In Time</li> </ul>
Security	<ul style="list-style-type: none"> <li>• OHSAS 18001</li> </ul>
Different stakeholders	<ul style="list-style-type: none"> <li>• Extended QMS (ISO 9004)</li> <li>• Environmental mgt system (ISO 14001)</li> </ul>
Diversity in the market	<ul style="list-style-type: none"> <li>• Extended QMS (ISO 9004)</li> </ul>
Turbulence	<ul style="list-style-type: none"> <li>• Extended QMS (ISO 9004), Agility</li> </ul>
Chain management	<ul style="list-style-type: none"> <li>• Extended QMS (ISO 9004), JIT</li> </ul>
Sustainability	<ul style="list-style-type: none"> <li>• Extended QMS (ISO 9004)</li> <li>• Sustainability guidance (ISO 26000)</li> </ul>
Path to excellence	<ul style="list-style-type: none"> <li>• Award models</li> </ul>



## ISO 9004 :2009 (DIS)

**Managing for sustained success  
of an organization –**

**A quality management approach**

**ISO 9004:2009 as an “integrator”  
of the different quality approaches  
and tools**



# Foundation: Quality Management Principles

- Customer focus
- Leadership
- Involvement of people
- Process approach
- System approach to management
- Continual improvement
- Factual approach to decision making
- Mutually beneficial supplier relations



## ISO 9004:2009 / Scope

This International Standard provides guidelines and tools for utilizing the principles of quality management to achieve sustained success.

It is applicable to all organizations, regardless of their size, type and activity.

This International Standard is not intended for certification, regulatory or contractual use.



## Purpose of ISO 9004:2009

“To help organizations who are users of ISO 9001 obtain long term benefit from the implementation of a **more broad-based** and **in-depth impact** quality management system”.



## Objectives for ISO 9004:2009

- Facilitate improvement in users' quality management systems
- Provide guidance to an organization for the creation of a quality management system that:
  - creates value for its customers, via the products it provides;
  - creates value for all other interested parties;
  - balances all interested parties viewpoints.



# Structure of ISO 9004:2009

1. Scope
2. Normative references
3. Terms and definitions
- 4. Managing for sustained success of an organization**
- 5. Strategy and policy formulation, planning & deployment**
- 6. Resource management**
- 7. Process management**
- 8. Monitoring, measurement, analysis and review**
- 9. Improvement, innovation and learning**

*The  
“essentials”*

**Annex A A self-assessment tool**

**Annex B Quality management principles**

**Annex C Correspondence between ISO 9004 and 9001**



## Ch 4. Managing for the sustained success of an organization

- **Organizational behavior:**  
focus, leadership, involvement
- **Organizational framework:**  
process and system approach
- **Organizational tools:**  
continual improvement, decisions based on facts
- **Organization's relationships:**  
suppliers and partners, mutual benefits

**Management responsibility!**



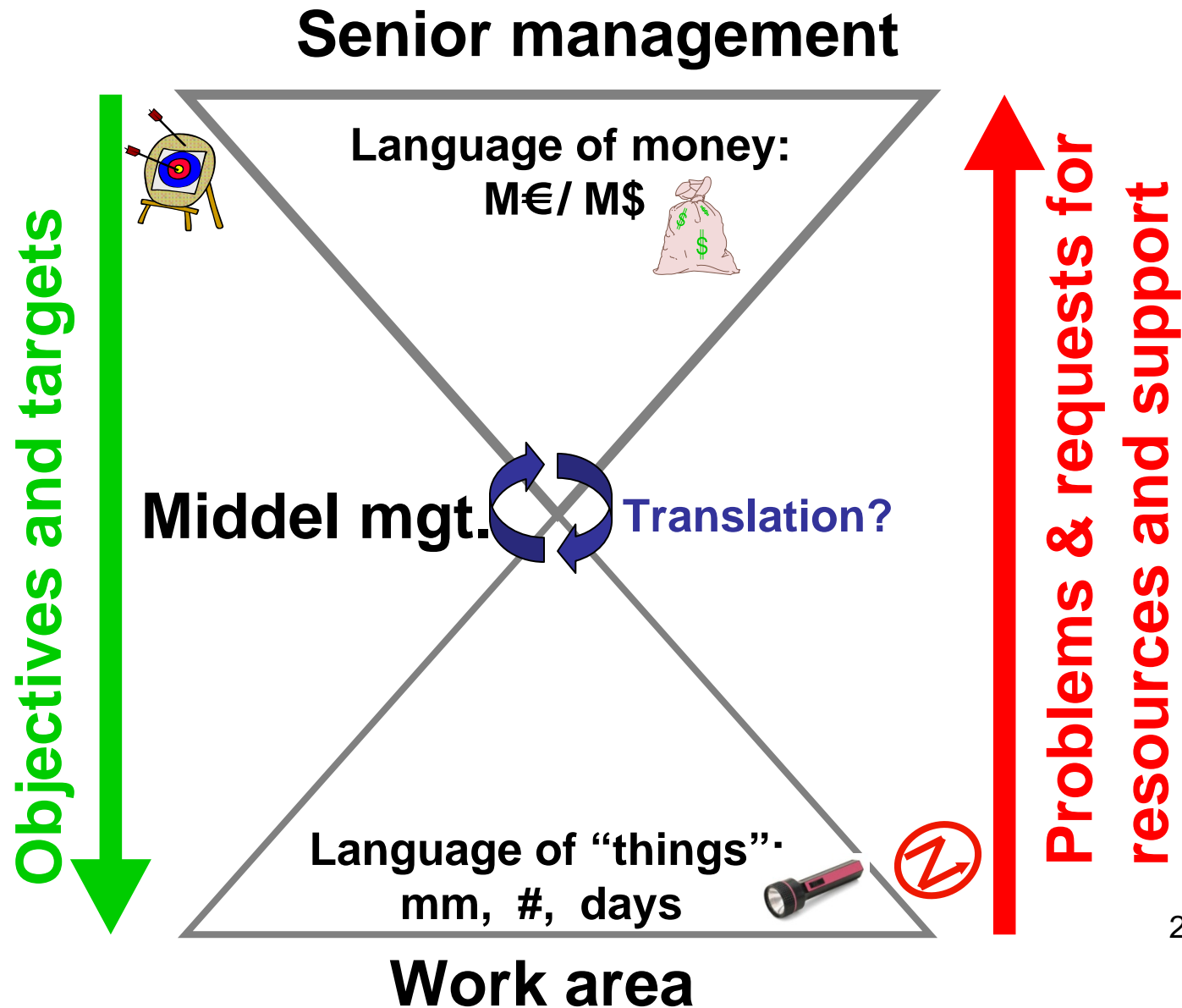
## Ch 5. Strategy and policy formulation, planning and deployment

- Create the right strategy (long term response to the interested parties needs and expectations)
- Formulate the right policy (principal guidelines for the organization)
- Evaluate different scenarios
- Deploy (realization)
- Communicate

**Management responsibility!**



# There are also two languages!





## Ch 6. Resource management

- General
- Financial resources
- Human resources (incl. competence and involvement)
- Suppliers, partners and partnerships
- Infrastructure
- Work environment
- Knowledge, information and technology
- Natural resources



## Ch 7. Process management

- Managing the organization's processes
- Process planning
- Process responsibility and authority
- Processes and their interrelations should be managed as a system! (networks!)
- Network described in a “map of processes”.
- Process planning including the needs to acquire new technologies.



## Ch 8. Monitoring, measurement, analysis and review

### “**Output matters**”

- Measure what matters – systematically!
- Gather ***suitable*** information.
- Monitor what is going on around you. Trends?
- Deliver facts to support decision making.
- Monitor progress towards objectives.
- Use of benchmarking.
- Check the effectiveness of the actions taken.

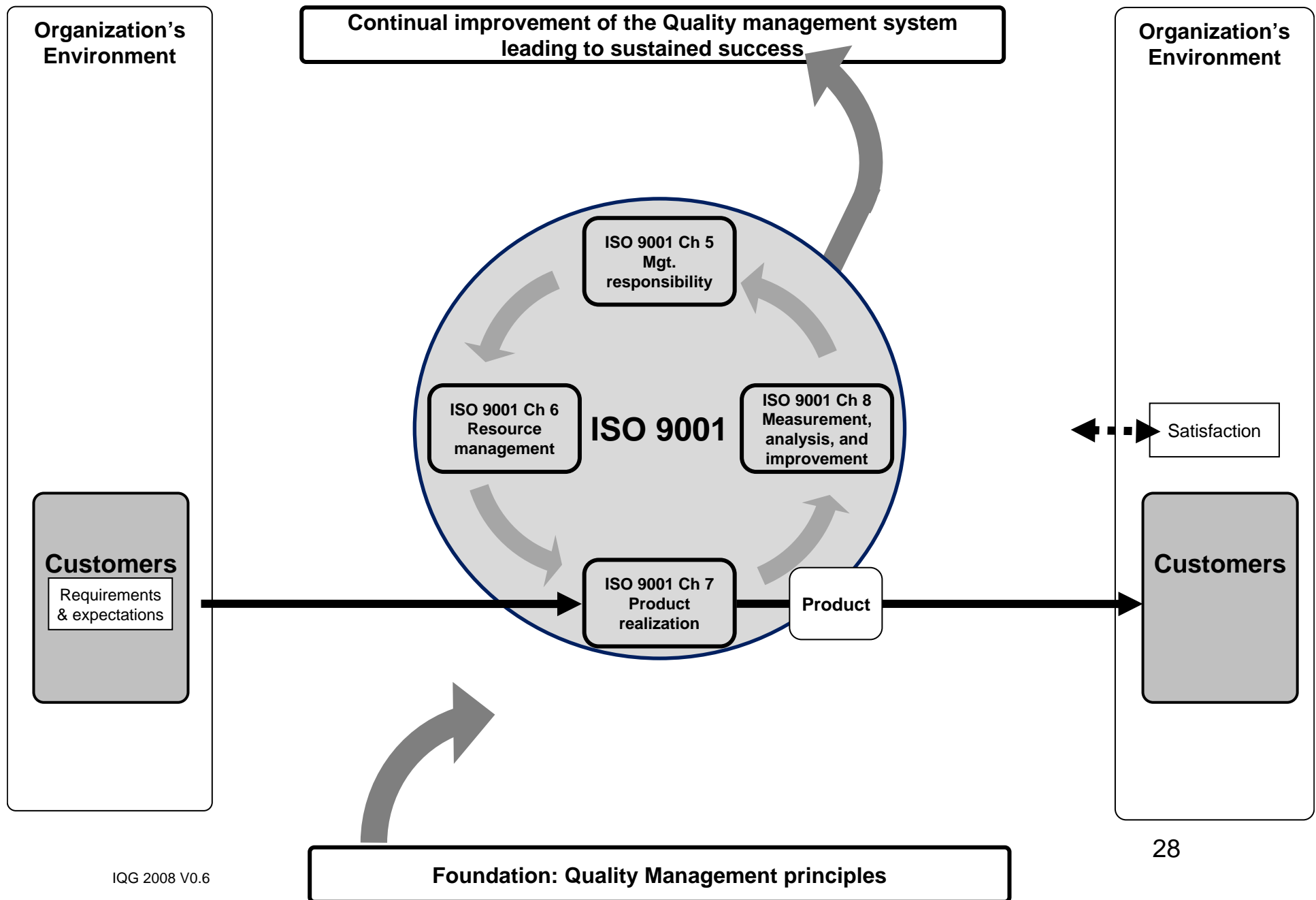


## Ch 9. Improvement, innovation, learning

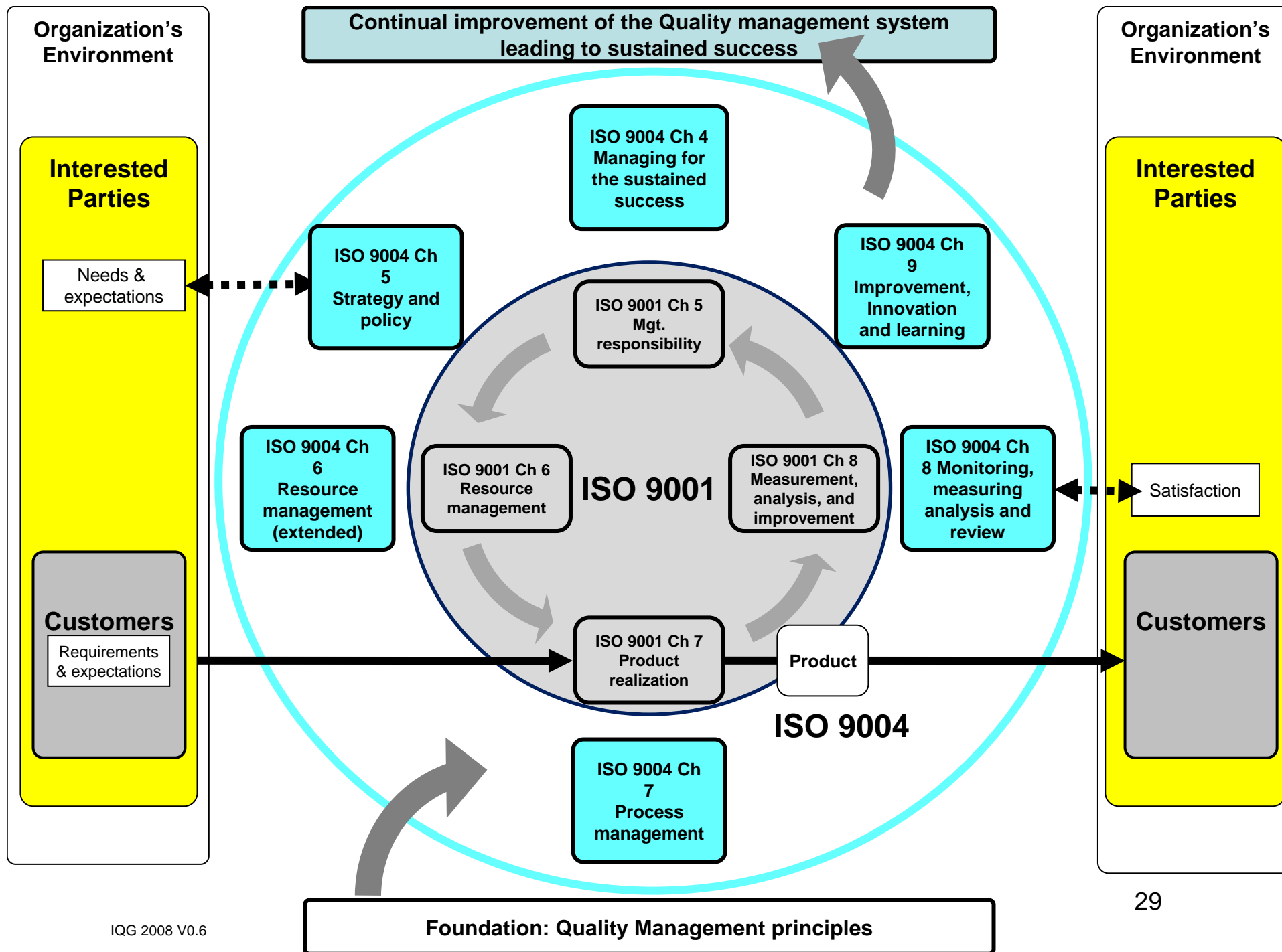
Should be applied to:

- Products,
- Processes and their interfaces,
- Organizational structures,
- Management system,
- Human aspects and culture
- Infrastructure, work relations & technology
- Organization's relations with its interested parties.





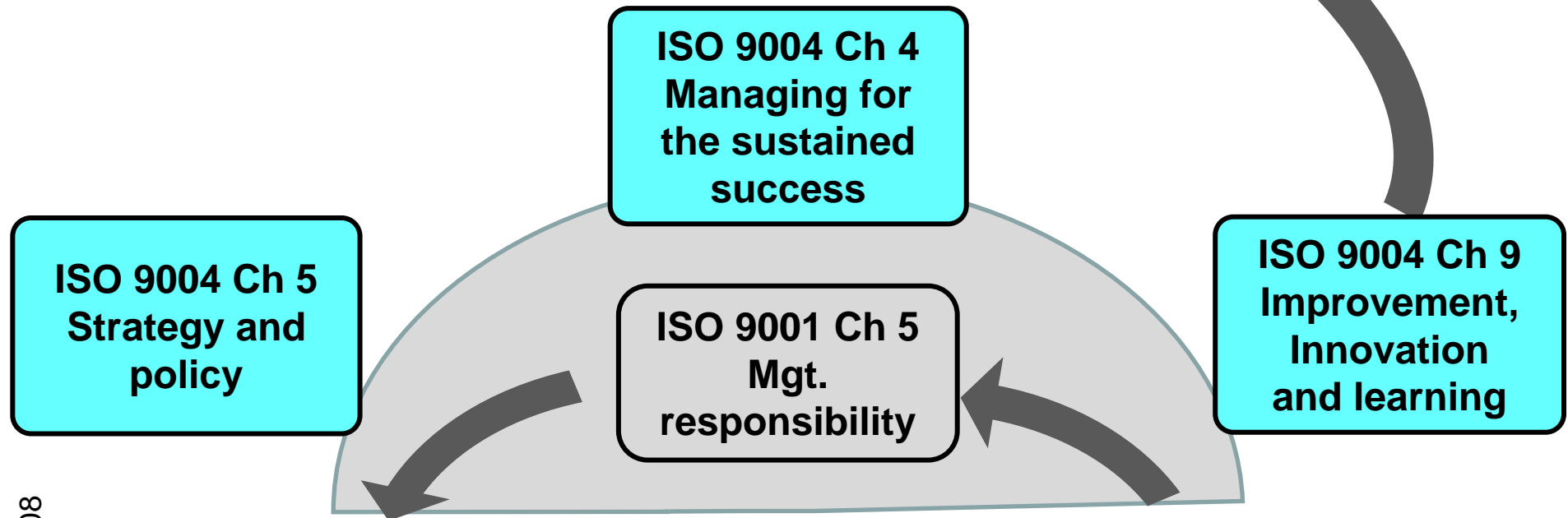






## Which way to go?

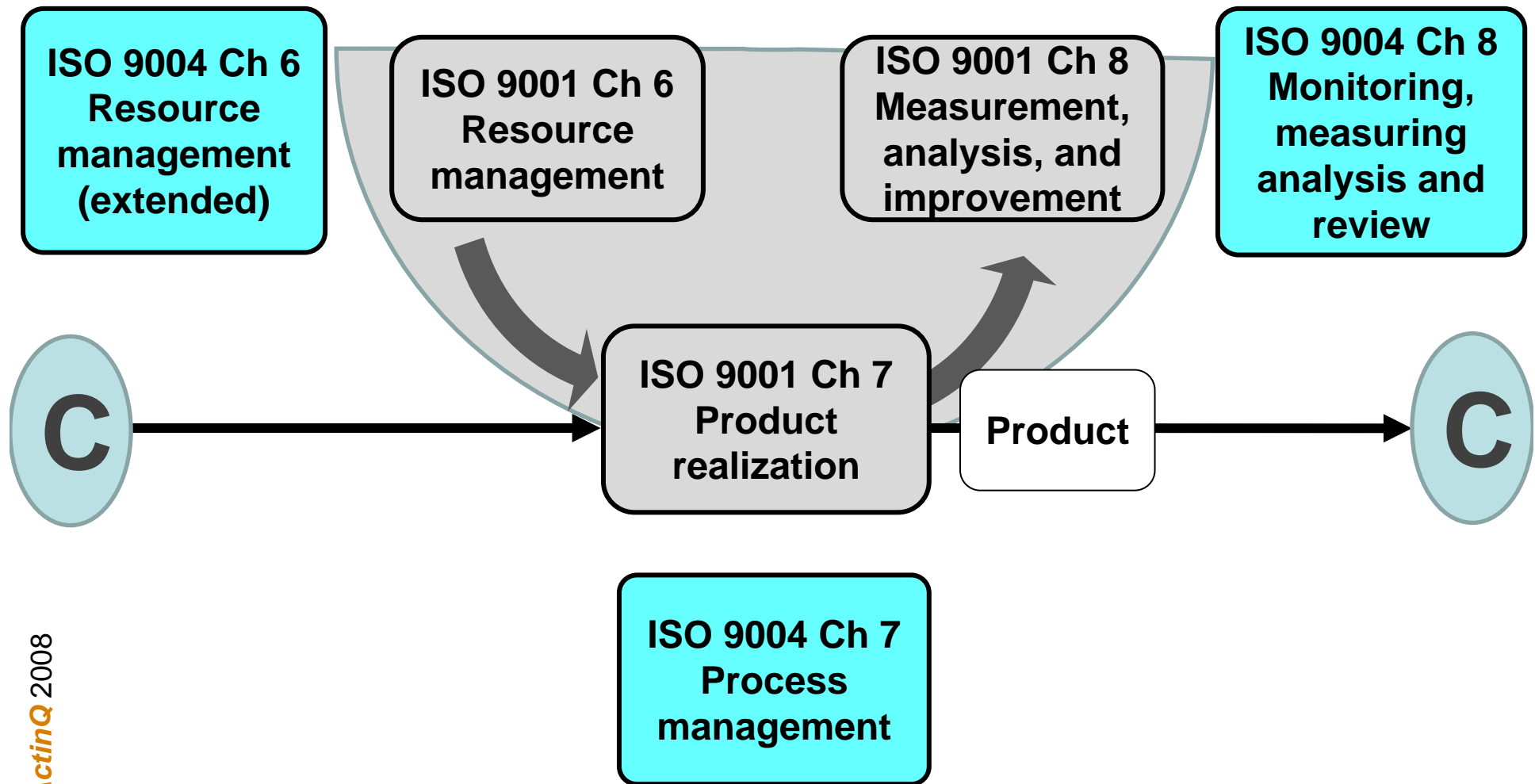
**Continual improvement of the Quality management system  
leading to sustained success**



**Foundation: Quality Management principles**

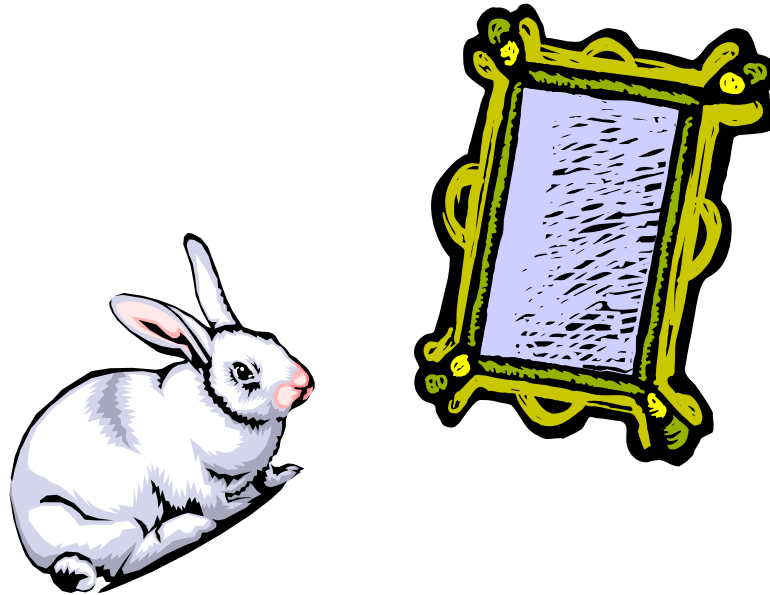


## Going the way chosen





Looking into the mirror, but what do I see?





Looking into the mirror, but what do I see?





# A1 Key elements self-assessment

## Five levels:

<b>1. Basic</b>	<b>2. Proactive</b>	<b>3. Flexible</b>	<b>4. Progressive</b>	<b>5. Achieving sustained success</b>
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## Six key elements:

- **Focus?**
- **Approach?**
- **Triggers?**
- **Activities and systems?**
- **Results?**
- **Learning?**



## A2 Self-assessment on detailed level

### Five levels:

<b>1. Basic</b>	<b>2. Proactive</b>	<b>3. Flexible</b>	<b>4. Progressive</b>	<b>5. Achieving sustained success</b>
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### Five focus areas (main chapters of 9004):

- 5. Strategy and policy formulation, planning & deployment**
- 6. Resource management**
- 7. Process management**
- 8. Monitoring, measurement, analysis and review**
- 9. Improvement, innovation and learning**

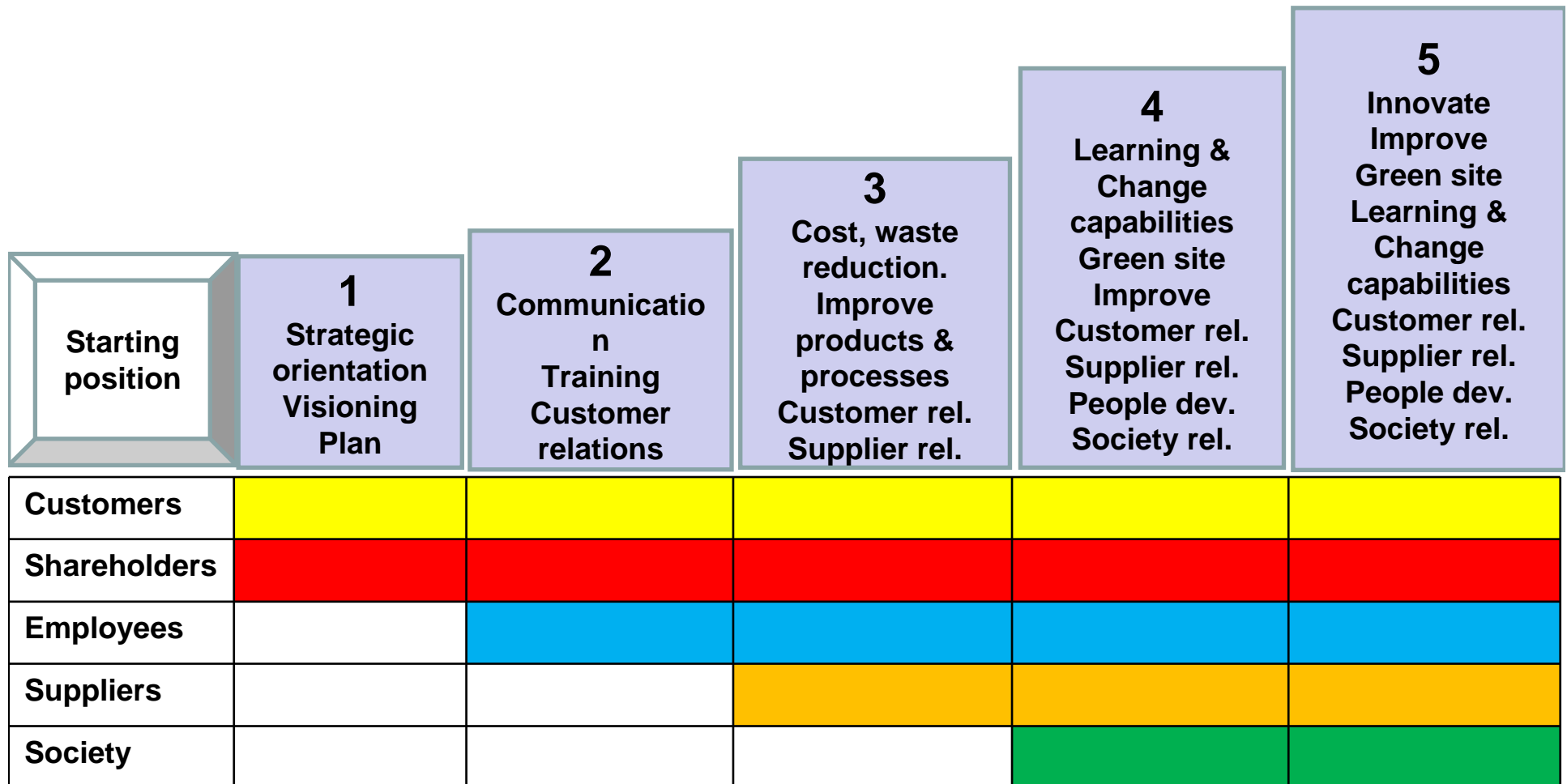


# What does it mean in simple words?





# One Roadmap towards sustained success





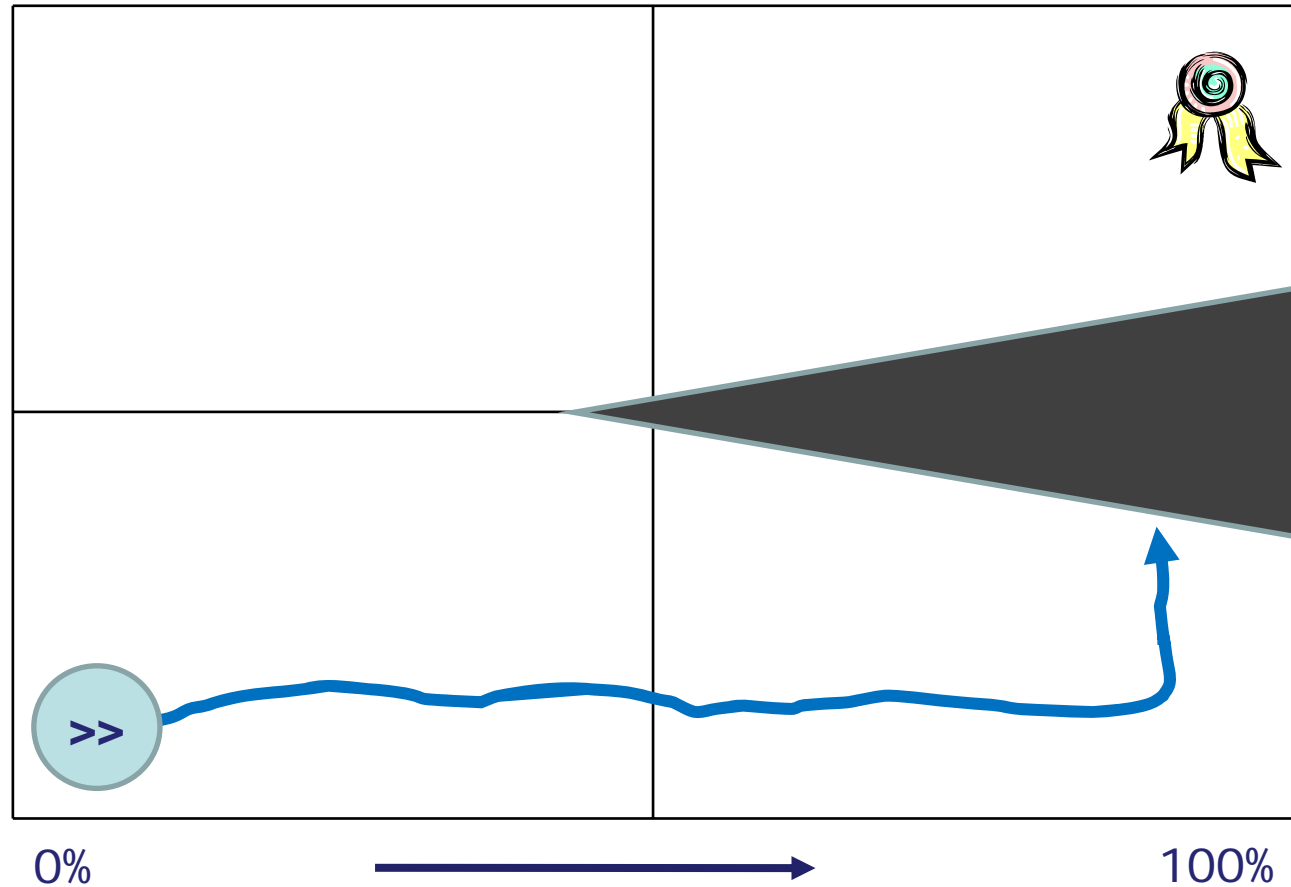
## Pitfall No. 1!

Ownership in  
the organization:  
We are working  
with .....

100%



0%



Documentation completed



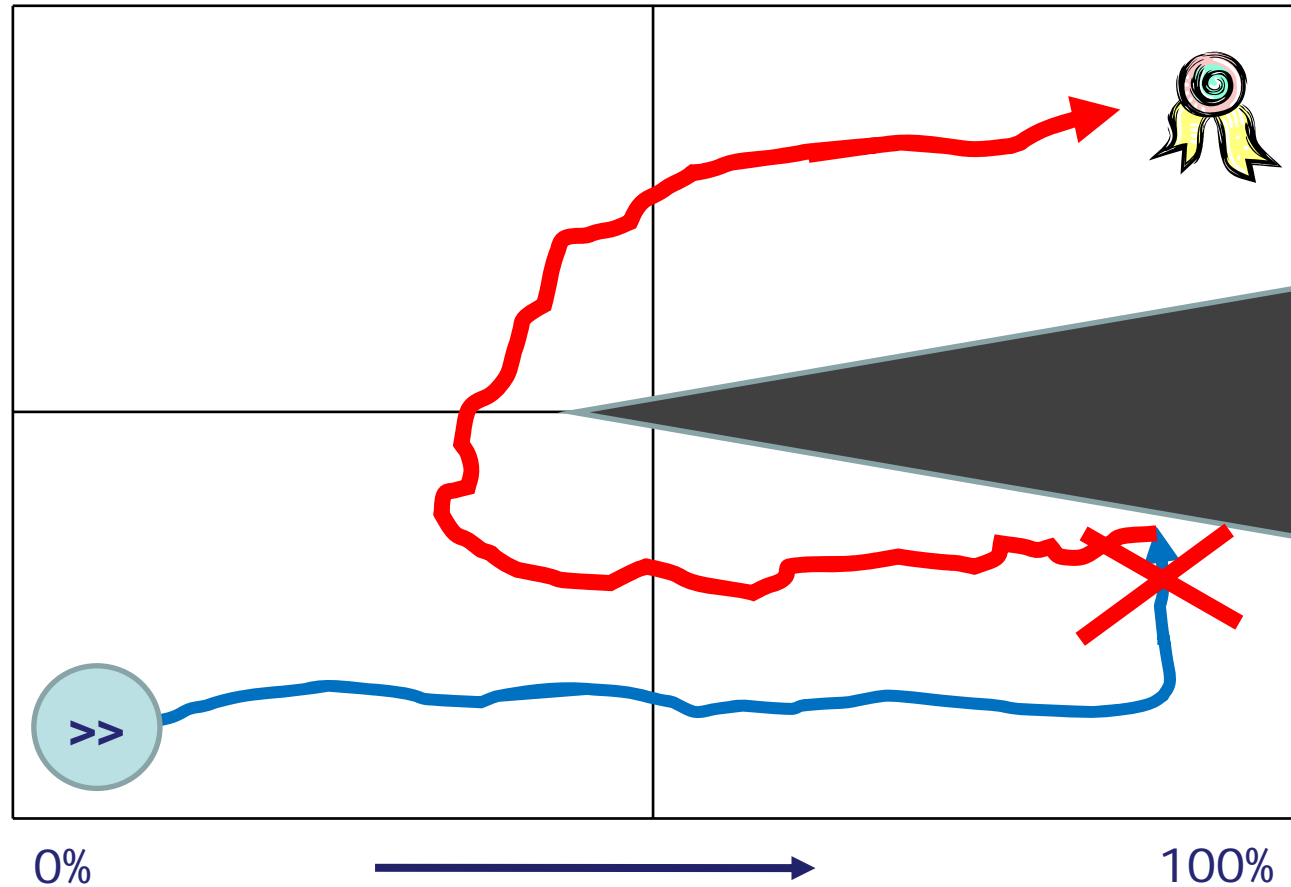
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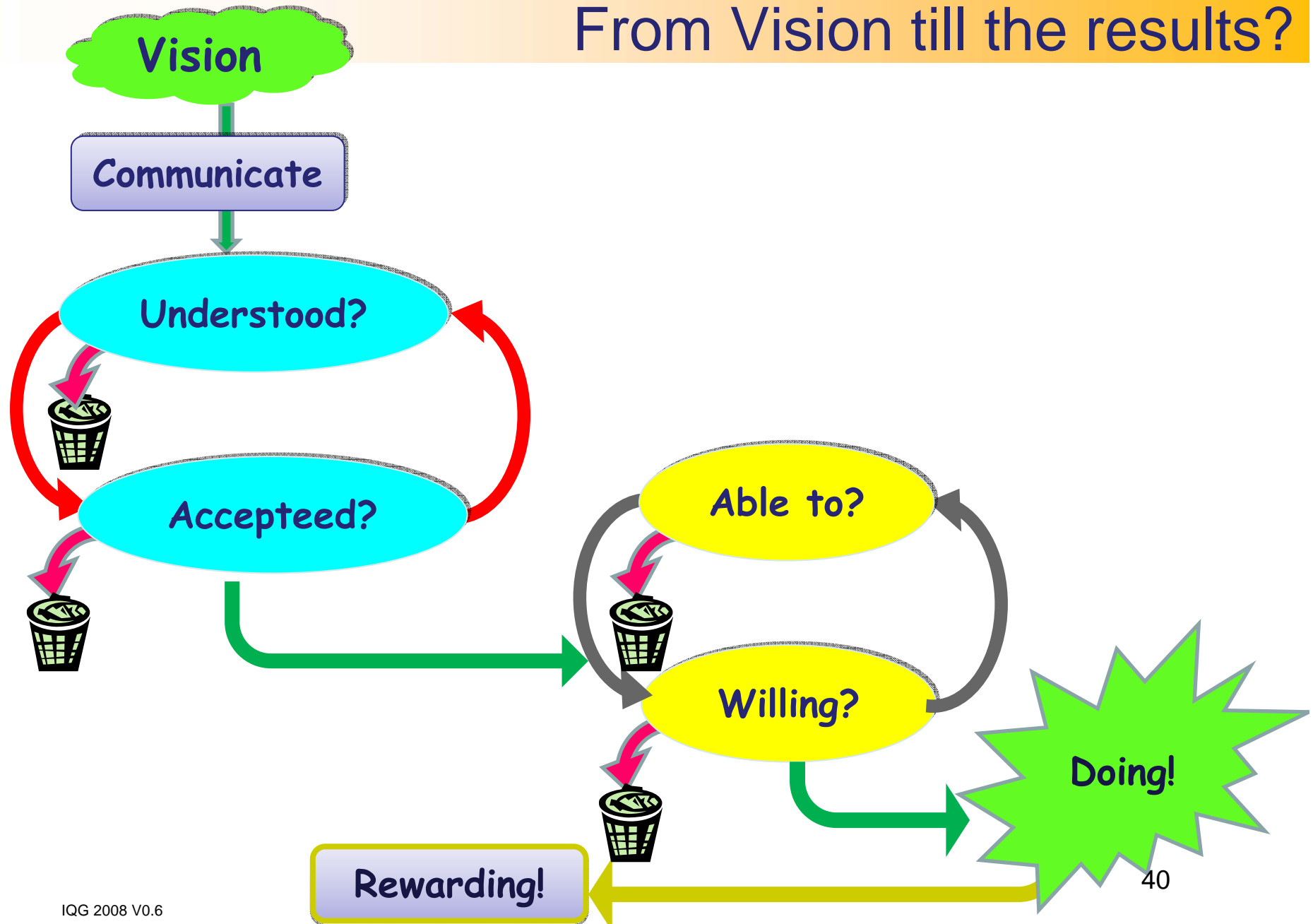


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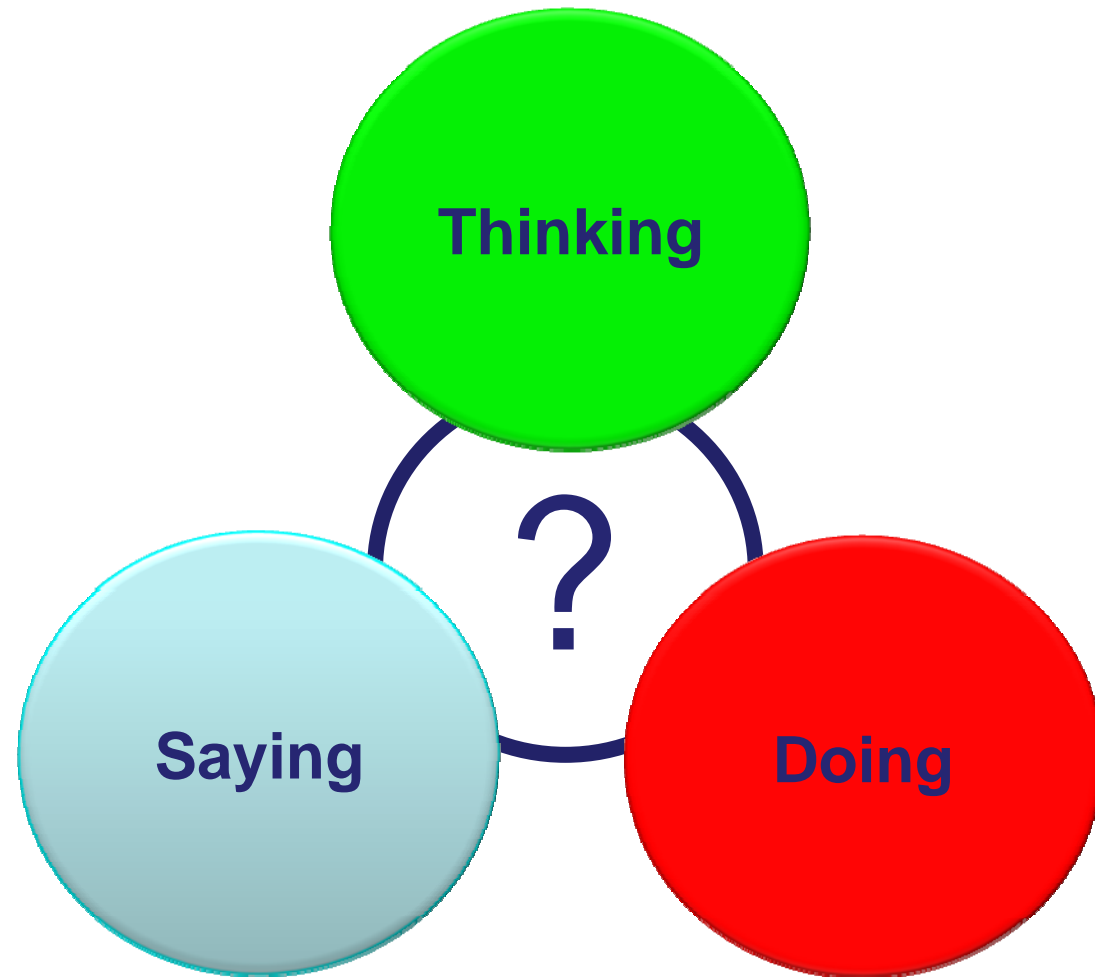


**Vision** From Vision till the results?





# Coherence of the behavior?





## The Ten golden implementation rules

1. **Be clear on what you want.**
2. **Identify obstacles.**
3. **Build a support network.**
4. **Set an example.**
5. **Take responsibility.**
6. **See the Big Picture.**
7. **Check every day.**
8. **Expert adversity.**
9. **Reward, especially first small wins.**
10. **Never give up!**

Anonymous





## Contact information

**ActinQ**

consulting, training & auditing in Quality

Bob Alisic

Mobile: +31 621 227 354

E-mail: [bob.alisic@ActinQ.nl](mailto:bob.alisic@ActinQ.nl)

Website: [www.ActinQ.nl](http://www.ActinQ.nl)