

# ISO 9001, History and Future

by

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# Egunon

C Corrie presentation to SPRI,  
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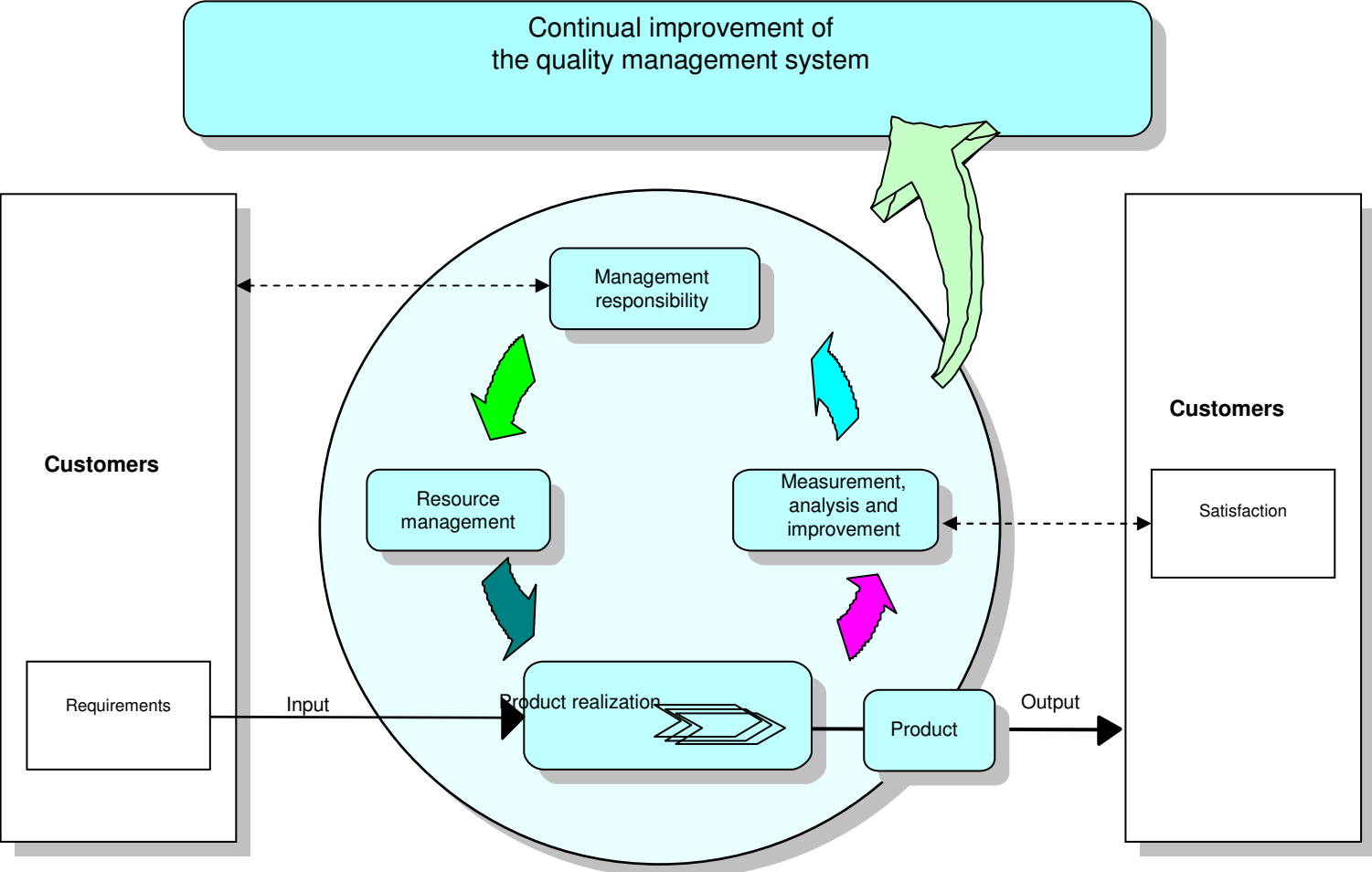
# History

- 1979 New work item proposal (based on BS 5750)
- 1987 The 1<sup>st</sup> edition of ISO 9001 was published, along with ISO 9002, ISO 9003
- 1994 A limited revision was published
- 2000 A major revision was published and ISO 9002, ISO 9003 withdrawn
- 2008 A minor amendment was published
- 2012 The next (major) revision has just started in Bilbao

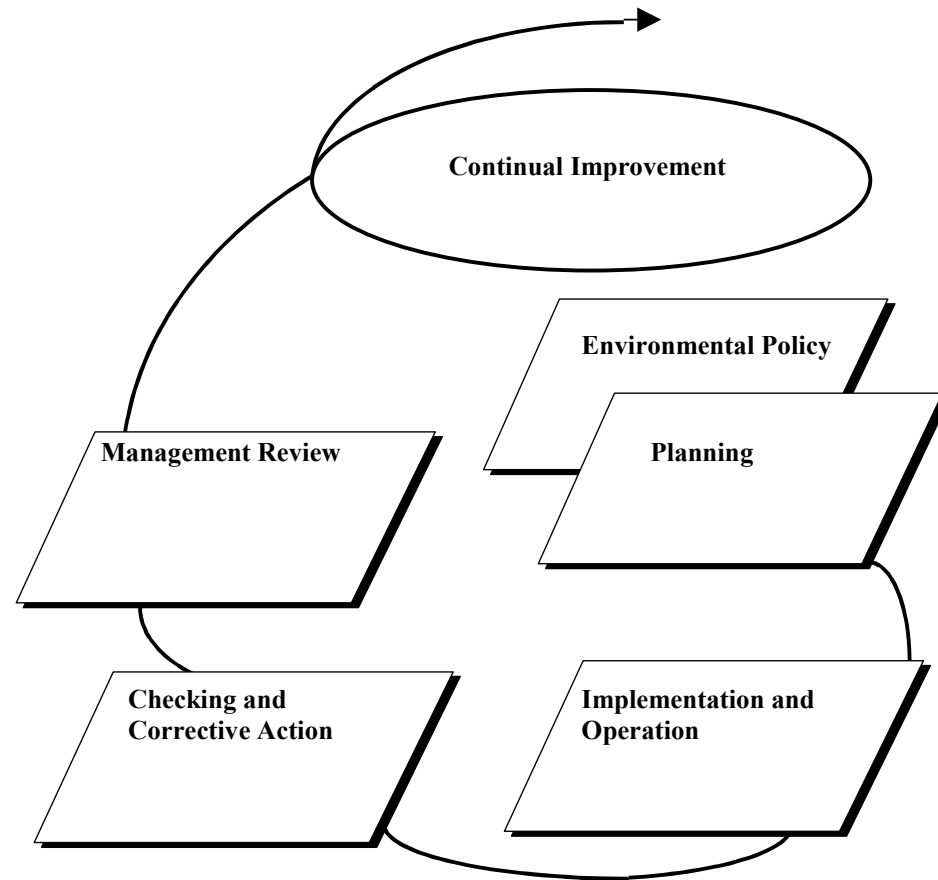
# History

- In 1991 ISO started discussing environmental management system standards
- In 1993 work was started to establish a common basis for all management system standards, using general management principles. Agreement could not be reached
- In 1990 “Vision 2000” proposed a process basis for ISO 9001
- In 1996 ISO 14001 was published, and did not look like ISO 9001, which led to complaints
- Work has continued since then to align the two standards, as well as many new ones

# ISO 9000 Process Approach structure



# ISO 14001 PDCA type structure



## Established Management (system) standards

ISO 9000 – Quality

ISO 14000 – Environment

ISO/IEC 27001 – Information Security

IEC 60300 – Dependability

ISO 15161- Food Safety (ISO 9000 and HACCP)

ISO 20000 – IT Services

ISO 22000 – Food Safety

ISO 15489 – Records Management

ISO 10006 - Project management

ISO 10007 – Configuration management

ISO/PAS 28001 – Security in the supply chain

ISO 30000 – Ship dismantling

ISO 31000 – Risk Management

ISO/IEC Guide 73 - Risk Management Terminology

ISO 26000 – Social Responsibility

## Established standards

ISO 22301 – Business continuity management

ISO 20121 – Sustainable event management

## Sectoral documents

ISO/TS 16949 – ISO 9000 Automotive

ISO/TS 29001 – ISO 9000 Oil and Gas

ISO/IEC 17025 – Laboratories (and ISO 9000)

ISO 13485 – Medical devices (and ISO 9000)

ISO/IEC 90003 – ISO 9000 Software

ISO/IWA 1 – ISO 9000 Healthcare

ISO/IWA 2 – ISO 9000 Education

ISO/IWA 4 – ISO 9000 Local Government

## Under development

ISO 55001 – Asset management

ISO 37500 – Outsourcing

Human Resources



## Outside of ISO /IEC

Malcolm Baldrige quality award, EFQM, Deming Prize

ILO OSH 2001/ BS 8800 / OHSAS 18001 – Occupational Health and Safety

SA 8000 – Social Accountability

AS 9100/EN 9100 – Aerospace quality

FIDIC Guide on quality for Consulting Engineers

International Maritime Organization quality documents

Chemical industries – Responsible cares (an IMS programme)

CMMI – software

IAEA – quality standards

UN de-mining quality standards

Other IEC, CEN and CENELEC MSS

## ISO/TMB/TAG13-JTCG “Joint Vision” – Agreed in 2010

All ISO management system “requirements” standards will be aligned and ISO will seek to enhance the compatibility of these standards, through the promotion of identical:

- *Clause* titles
- Sequence of *clause* titles
- Text, and
- Terms and definitions

that are permitted to diverge only where necessitated by specific differences in managing their individual fields of application.

The use of this approach for future revisions and new management system “requirements” standards will be targeted at increasing the value of these standards to users.

# **ISO/TMB/TAG13-JTCG “High Level Structure”**

**– Agreed in 2011, added to ISO/IEC Directives in 2012**

## Introduction

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

## Why does it take so long between revisions ?

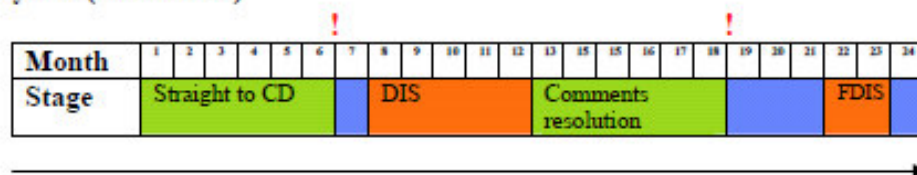
- ISO requires a maximum period of 5 years between reviews of standards
- The certification cycle is 3 years between full reassessments. Users do not want changes every full reassessment, so ask for the maximum review period.
- The underlying concepts for quality do not change
- The development of a standard takes about 3 years



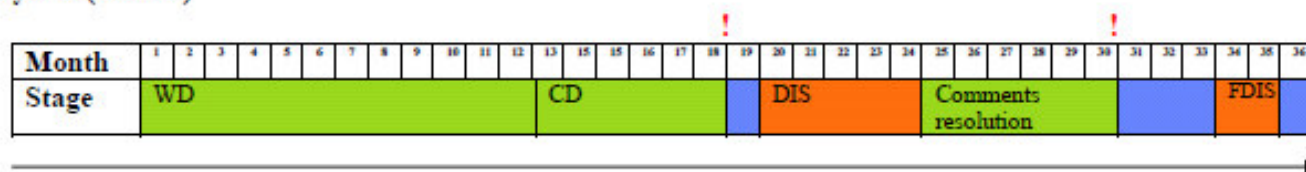
# ISO target date planner

This target date planner shows you the three main development tracks for project managing the development of an ISO standard. It will help you choose the track and then set the target dates you need to meet for your standards to be delivered to the market on time. The times shown are the maximum for each stage and can be shortened whenever possible.

## 2 years (Accelerated)



## 3 years (Default)



## 4 years (Extended)



**Approval**  
Approval at DIS and FDIS stages requires two thirds of P members of the TC to vote yes and not more than a quarter of all votes cast to be negative.

100% approval at DIS can mean straight to publication if the committee agrees.

Explanation

**ISO Technical Committee time:**  
Document being developed in the relevant committee.

**ISO Central Secretariat time:**  
Document being processed (e.g. evaluation, editing and proofreading).

**ISO Member body time:**  
Document circulated to ISO member bodies for DIS/FDIS vote.

! Months marked with this are the key **limit dates**. Missing them means action is needed to avoid eventual cancellation of the project

WD = Working Draft

CD = Committee Draft

DIS = Draft International Standard

FDIS = Final Draft International Standard

# ISO/CD 9001 in 1999

- 4500 comments were received
- 600 pages of text
- 3 weeks pre-working
- 5 day meeting to agree the changes

We hope it will not be the same again  
(ISO 26000 received 7000 comments)

# ISO/TC 176/SC2/WG24 meeting in Bilbao, 18 – 22 June 2012

- Developed a “Design Specification” for the revision of ISO 9001
- Developed a Project Plan, based on a 3 year development path
- Developed a “Preliminary draft” of ISO 9001 in the “High Level Structure”

A “new work item proposal” ballot is to be conducted using these as supporting documents

- Set tasks to review the key inputs before the next meeting (November)

# Adding value

- Fitting the current ISO 9001:2008 into the High Level Structure would not be considered to add sufficient value for many users (1m ISO 9001 certificates, versus 200k ISO 14001 certificates)
- The revision has to address new quality concepts, and provide a sound basis for the next 15 years.



# New Concepts

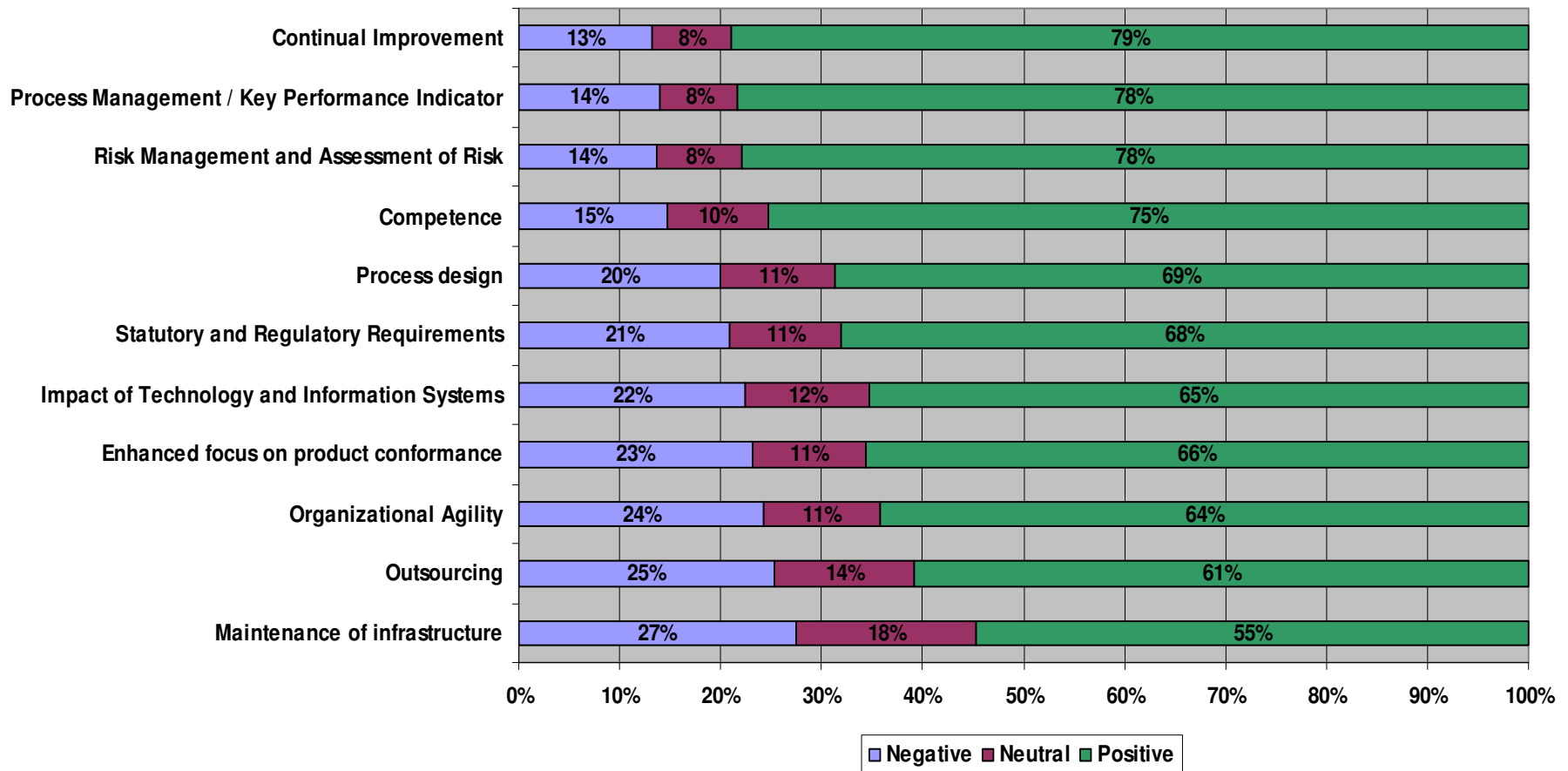
- During 2009 to 2011 brainstorming and research was undertaken on “new concepts” that could be used in ISO 9001 (e.g. examining risks)
- These were analyzed and recommendations made
- Some were taken into the High Level Structure

# ISO 9000 User Survey

- Conducted during 2010 – 2011
  - 11, 700 responses
  - Tested new concepts with users
  - Tested having more than one “requirements” standard (e.g. having ISO 9002 and ISO 9003 again).
- Clear feedback that only 1 standard is wanted.

**11.9 - How important is it to enhance the current content in ISO 9001 with the following concepts in any future revision?**

(Based on 8505 answers)



# Design Specification

- Scope to largely remain unchanged:  
“the achievement of customer satisfaction through the provision of products that meet customer and regulatory requirements”
- ISO 9001 should continue to be generic
- Maintain the focus of managing processes
- ISO 9001 should be readily understandable, and translatable.
- ISO 9001 should use the High Level Structure

# Design Specification

The changes to ISO 9001 should:

- be relevant to quality management system requirements
- increase confidence in an organization's ability to provide conforming product and/or service
- enhance an organization's ability to satisfy its customers
- enhance customer confidence in quality management systems based on ISO 9001.

# (In contrast)

Suggests were received to

- Expand the scope to reference sustainability and social responsibility
- Reduce the scope back to focussing purely on quality assurance, not quality management

# ISO/TMB/TAG13-JTCG “High Level Structure”

## Introduction

1. Scope
2. Normative references
3. Terms and definitions
  
4. Context of the organization
5. Leadership
6. Planning
7. Support (*includes Resources*)
8. Operation
9. Performance evaluation
10. Improvement

*Note – no model diagram is available at this time*

## **4. Context of the organization**

*(formerly, part of Management Review)*

### **4.1 Understanding the organization and its context**

The organization shall determine external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended outcome(s) of its XXX management system.

### **4.2 Understanding the needs and expectations of interested parties**

*(e.g. customer requirements, legal and regulatory requirements)*

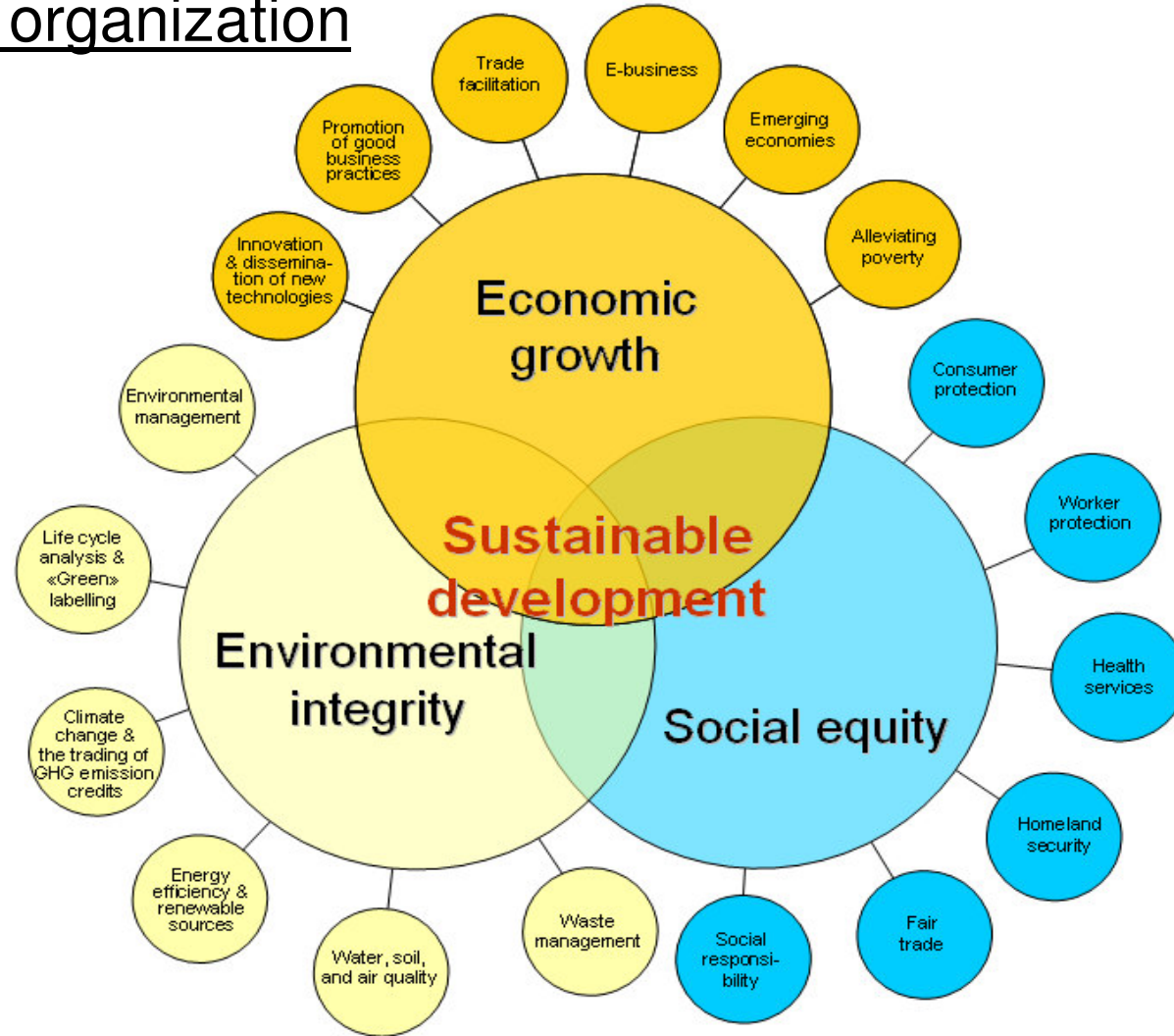
### **4.3 Determining the scope of the XXX management system**

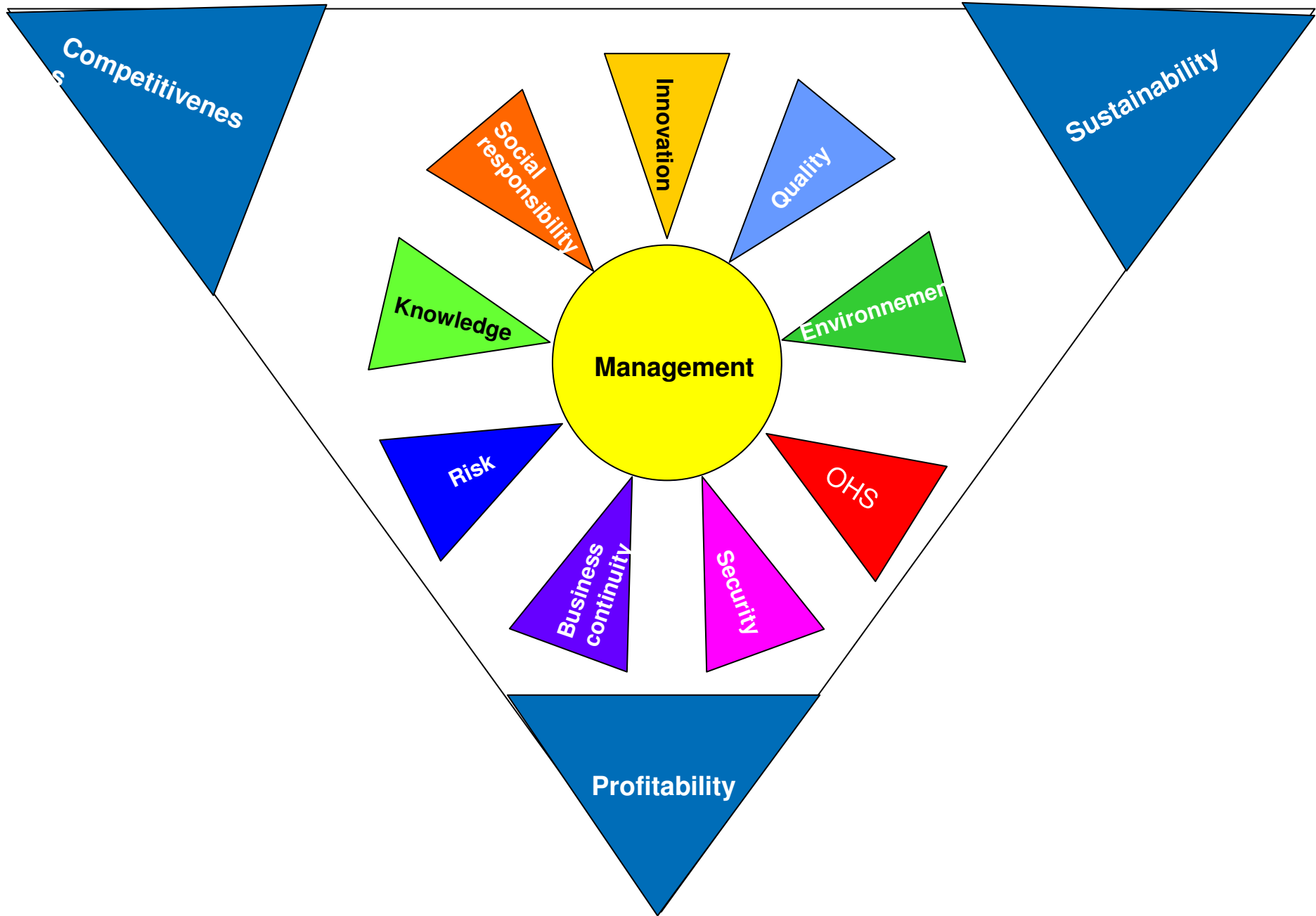
### **4.4 XXX management system *(i.e. establish the MS)***



## 4. Context of the organization

Identify the issues that can affect your organization, and which of those issues the MS needs to control





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## 5. Leadership

### 5.1 Leadership and commitment

Top management shall demonstrate leadership and commitment with respect to the XXX management system by

- ensuring that policies and objectives are established for the XXX management system and are compatible with the strategic direction of the organization
- ensuring the integration of the XXX management system requirements into the organization's business processes
- ensuring that the resources needed for the XXX management system are available
- communicating the importance of effective XXX management and of conforming to the XXX management system requirements
- ensuring that the XXX management system achieves its intended outcome(s)
- directing and supporting persons to contribute to the effectiveness of the XXX management system
- promoting continual improvement
- supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

## 5.2 Policy

### 5.3 Organizational roles, responsibilities and authorities

Top management shall ensure that the responsibilities and authorities for relevant roles are assigned and communicated within the organization.

Top management shall assign the responsibility and authority for:

- ensuring that the XXX management system conforms to the requirements of this International Standard: and

- reporting on the performance of the XXX management system to top management.

*Note – no “Management representative”*

## 6. Planning

### 6.1 Actions to address **risks and opportunities**

When planning for the XXX management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to

- assure the XXX management system can achieve its intended outcome(s)
- prevent, or reduce, undesired effects
- achieve continual improvement.

The organization shall plan:

- a) actions to address these risks and opportunities, and
- b) how to

- integrate and implement the actions into its XXX management system processes
- evaluate the effectiveness of these actions.

### 6.2 XXX objectives and planning to achieve them

## **7. Support**

### **7.1 Resources**

### **7.2 Competence**

### **7.3 Awareness**

Persons doing work under the organization's control shall be aware of

- the XXX policy
- their contribution to the effectiveness of the XXX management system, including the benefits of improved XXX performance
- the implications of not conforming with the XXX management system requirements.

### **7.4 Communication**

## **7.5 Documented information**

### **7.5.1 General**

The organization's XXX management system shall include

- documented information required by this International Standard
- documented information determined by the organization as being necessary for the effectiveness of the XXX management system.

### **7.5.2 Creating and updating**

### **7.5.3 Control of documented Information**

*Note – no “Control of documentation / records”, or documented procedures*

## **8. Operation**

### **8.1 Operational planning and control**

The organization shall plan, implement and control the processes needed to meet requirements, and to implement the actions determined in 6.1, by

- establishing criteria for the processes
- implementing control of the processes in accordance with the criteria
- keeping documented information to the extent necessary to have confidence that the processes have been carried out as planned.

The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

The organization shall ensure that outsourced processes are controlled.

*Note – the focus on processes*



## **9. Performance Evaluation**

### **9.1 Monitoring, measurement, analysis and evaluation**

### **9.2 Internal Audit**

### **9.3 Management review**

## **10.Improvement**

### **10.1 Nonconformity and corrective action**

### **10.2 Continual improvement**

*Note – no “Preventive action”*

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*For*

*Your attention*

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