



Some insights into the new ISO 9001:2015

Hong Kong, November 25th 2015

Dr Nigel H Croft

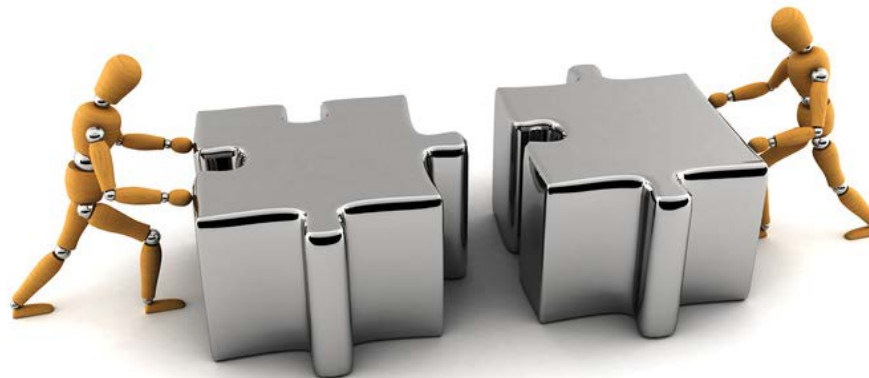
Chairman of ISO/ TC 176/ SC 2 (Quality Systems)

Member of ISO/TMB/JTCG (Joint Technical Coordination Group)



ISO Mission

- ISO develops high quality voluntary International Standards which facilitate international exchange of goods and services, ***support sustainable and equitable economic growth, promote innovation*** and protect health, safety and the environment



ISO Technical Committee TC 176

- “ISO” = International Organization for Standardization
 - Confederation of National Standards Bodies
 - Based in Geneva
- Standards development work is done by Technical Committees comprising experts nominated by their national standards body or liaison organization.
- “TC 176” = Technical Committee Number 176 for Quality Management and Quality Assurance
 - “TC 176/SC 2” is the subcommittee responsible for ISO 9001, ISO 9004 and other guidance documents



Overall Scenario of ISO/TC176

- Development of generic quality management system standards that have broad applications:
 - all market sectors
 - large and small, private and public organizations
- Approx. 1.1 million certifications to ISO 9001 worldwide

BUT

- It's about more than just “certification”
“Certification to ISO 9001” should be a result of a well-implemented quality management system!

TC 176/SC 2 Vision

“SC2’s products are *recognized and respected worldwide*, and *used by organizations as an integral component of sustainable development*”





TC176/SC2 Mission

- To ***develop, maintain and support a portfolio of products that enable organizations to improve their performance*** and to benefit from the implementation of a robust quality management system.
- To ***establish generic quality management system requirements*** that provide the foundations to build confidence in goods and services delivered throughout the supply chain to organizations and people worldwide.
- To ***provide guidance and support***, where needed, to ensure the continued credibility of our products.



Management System

“Set of interrelated or interacting elements of an organization to establish policy and objectives *and to achieve those objectives*” (ISO 9000:2015 definition)

In other words..... ***RESULTS FOCUSED***

- ISO 9001 – “Consistent, conforming products”
- ISO 14001 – “Prevention of pollution”
- ISO 45001 – “Safe working conditions”
- ISO 50001 – “Efficient energy usage”
- ISO 22000 – “Safe food”
- etc

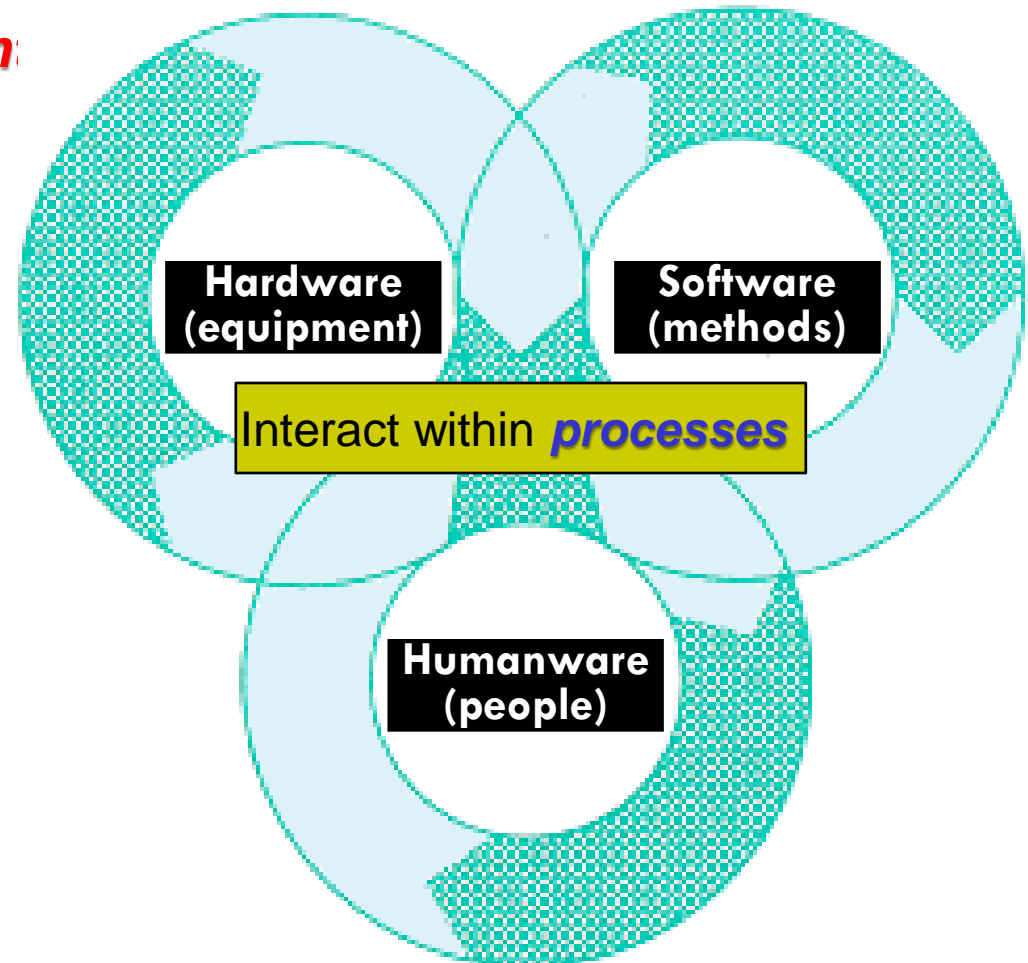


“Quality Management System”

A “*documented system*” –
NOT a “*system of documents*”

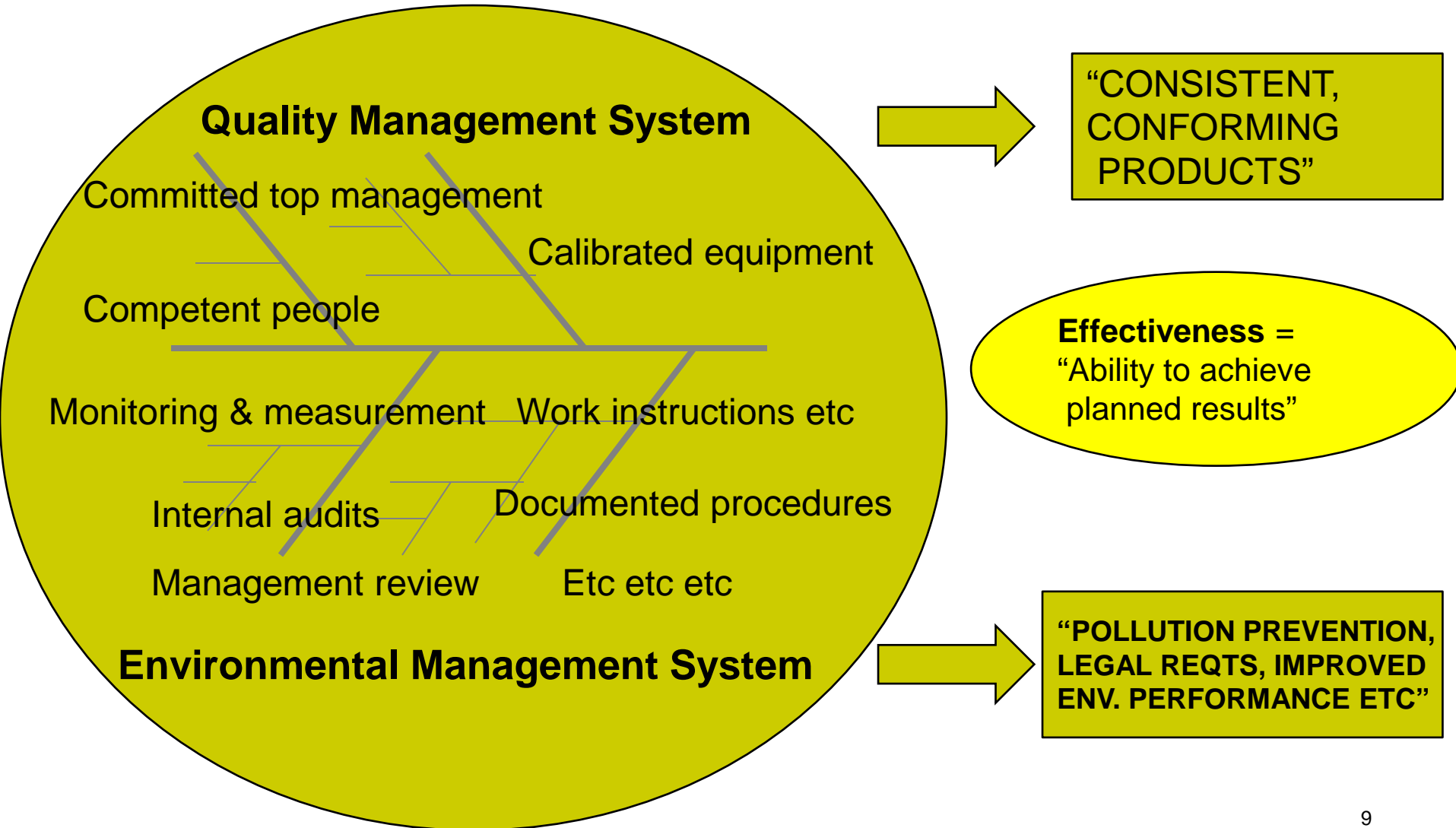
IMPORTANT:

- System should not be “carved in stone”
- Should allow *flexibility* and *agility* to:
 - seize *opportunities* as they arise
 - adapt to the *risks* posed by the ever-changing business context





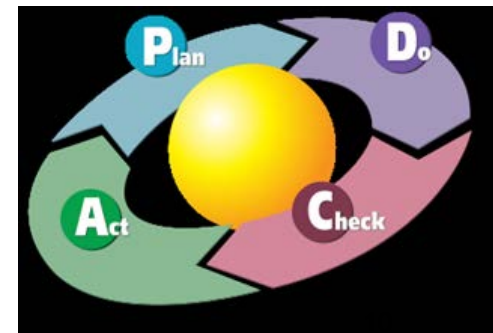
“Cause and effect”





Three Core Concepts in Modern Management Systems

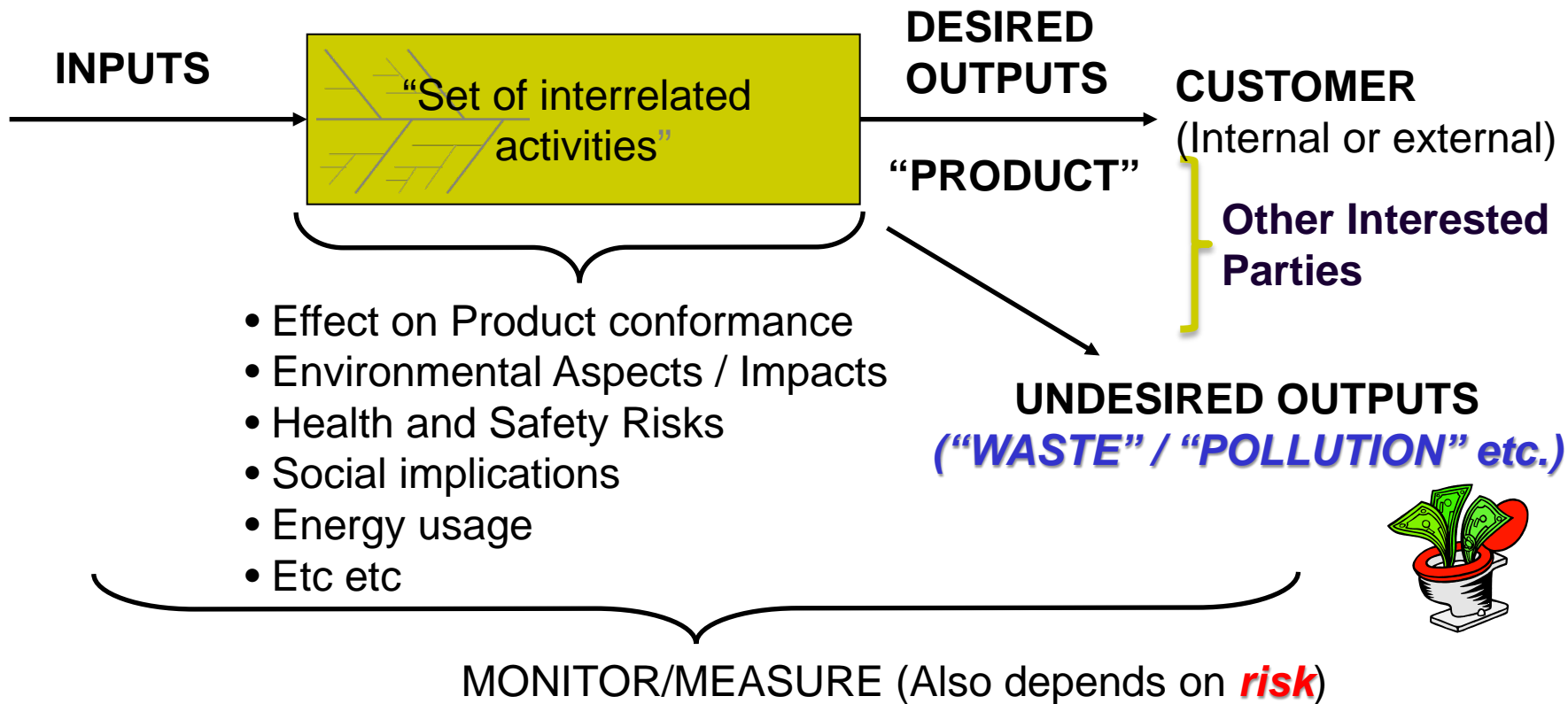
- Identify the **processes** needed to achieve the planned results
- Continually monitor the **risks** (“Risk-based thinking”)
 - Understanding “Cause and Effect”
- Manage the processes and the system using **“PDCA”**



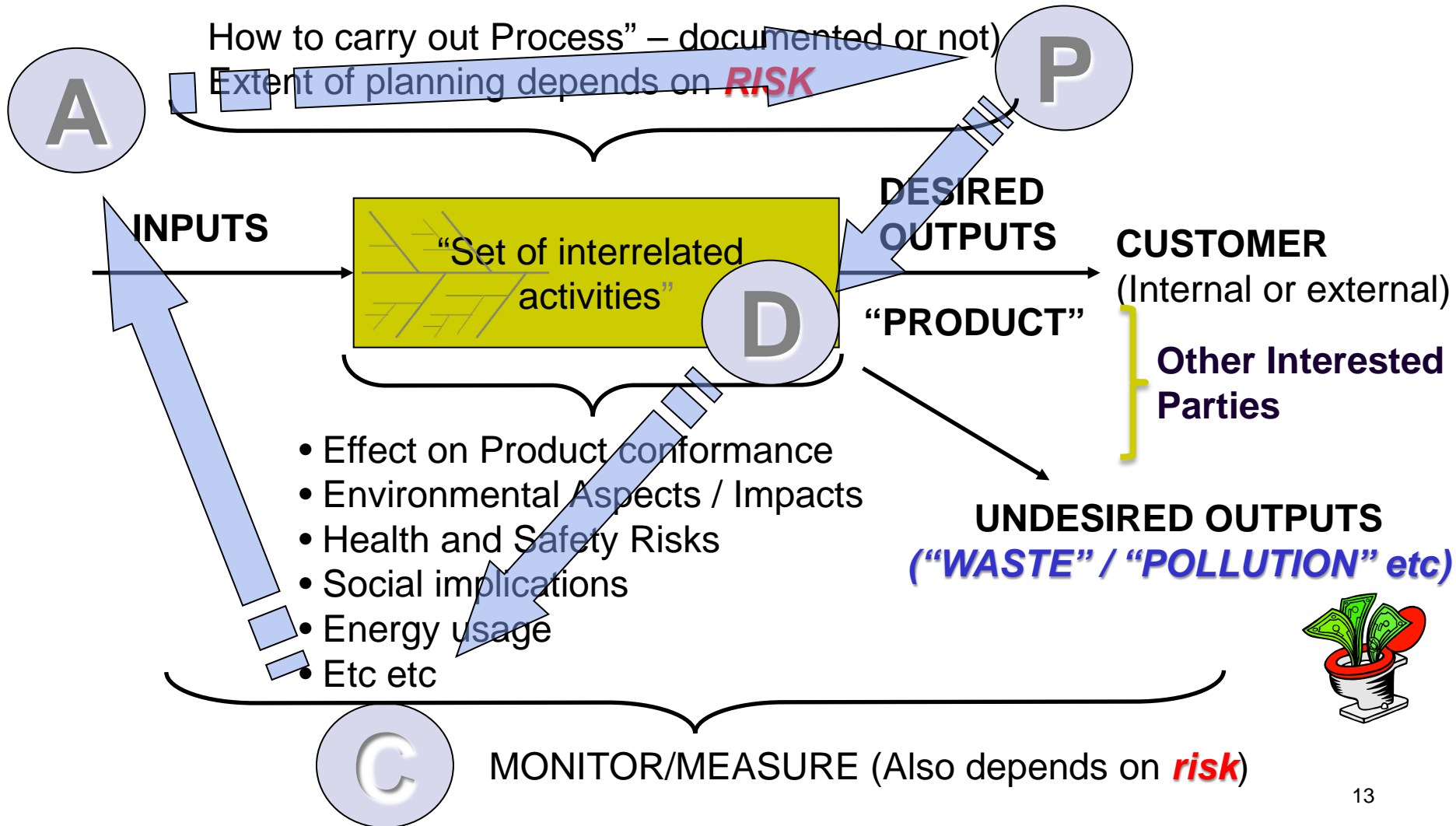


Generic Process

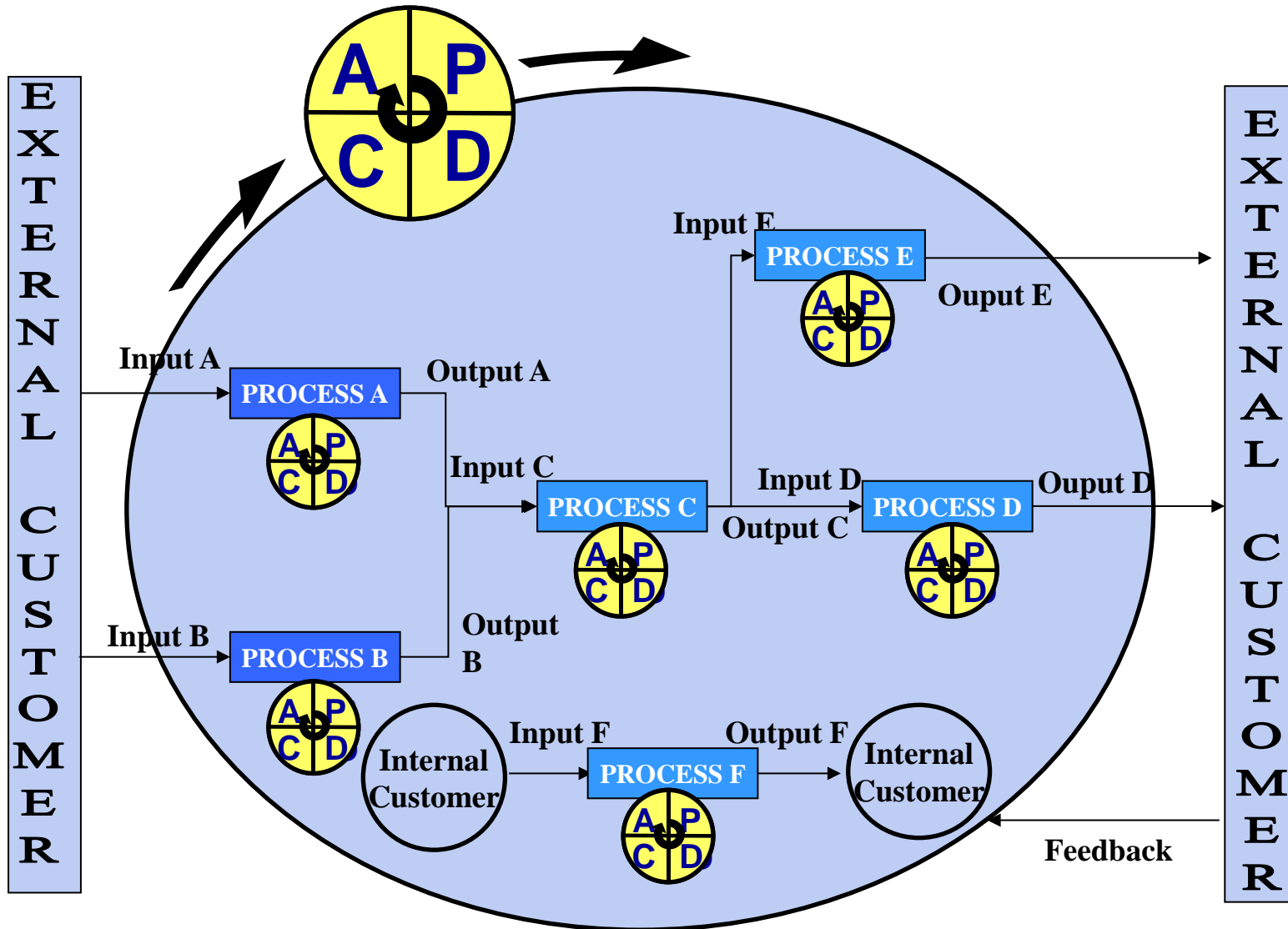
How to carry out Process” – documented or not)
 Extent of planning depends on **RISK**



Generic Process



System of processes

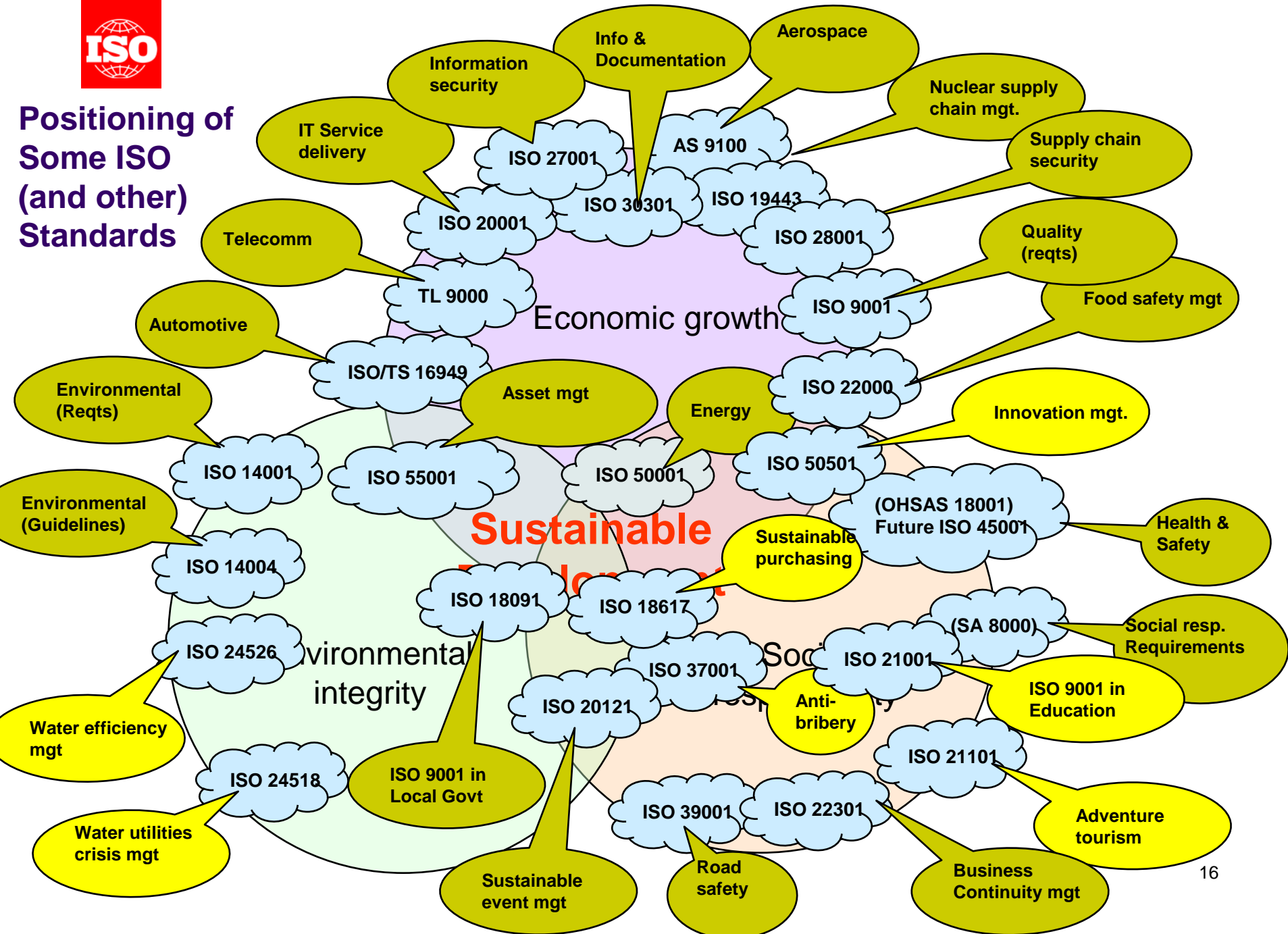




Harmonization of management system standards



Positioning of Some ISO (and other) Standards





Alignment of management system standards

- ISO Joint Technical Coordination Group (“JTTCG”):
 - Joint vision for management system standards
 - High level structure for all ISO management systems standards
 - Identical sub-clause titles under the high level structure
 - Generic core vocabulary for management system standards
- Aim is to make life easier for those who wish to have a “single management system”

ISO Directives “*Annex SL*”

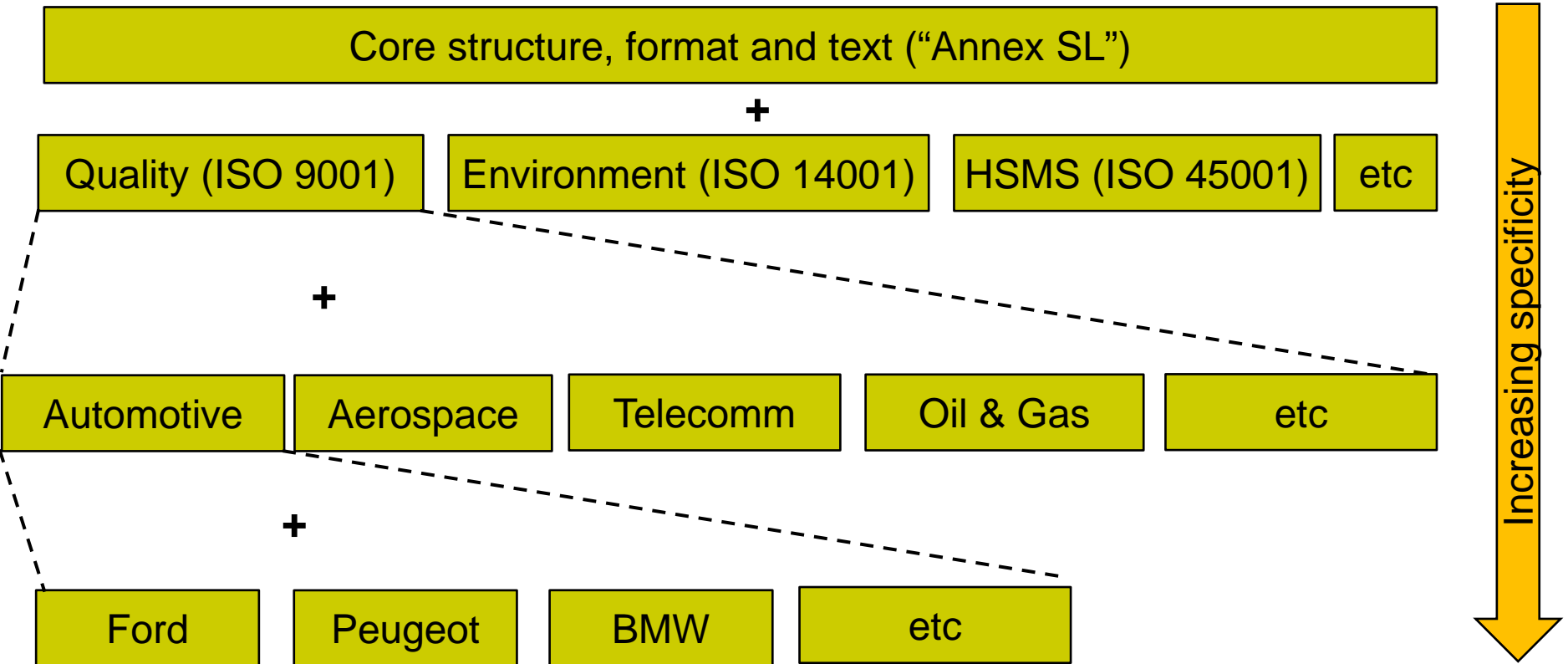
- Incorporates the recommendations of the JTCG work
- Defines the common structure and format for all new ISO management system standards *and revisions to existing standards*
- Common text (approx 30% or more of each standard will be identical text)
- Significant impact on revisions of ISO 9001 and ISO 14001

“Annex SL” High Level Structure

1. **Scope**
2. **Normative references**
3. **Terms and definitions**
4. **Context of the organization**
 - *Understanding the organization and its context*
 - *Needs and expectations of interested parties*
 - Determining the scope
 - Management System
5. **Leadership**
 - *Leadership and commitment*
 - Policy
 - Roles, responsibility and authority
6. **Planning**
 - *Actions to address risks & opportunities*
 - Objectives and plans to achieve them
7. **Support**
 - Resources
 - Competence
 - Awareness
 - Communication
 - Documented information
8. **Operation**
 - Operational planning and control
9. **Performance evaluation**
 - Monitoring, measurement, analysis & evaluation
 - Internal audit
 - Management review
10. **Improvement**
 - Non conformity and corrective action
 - Continual Improvement



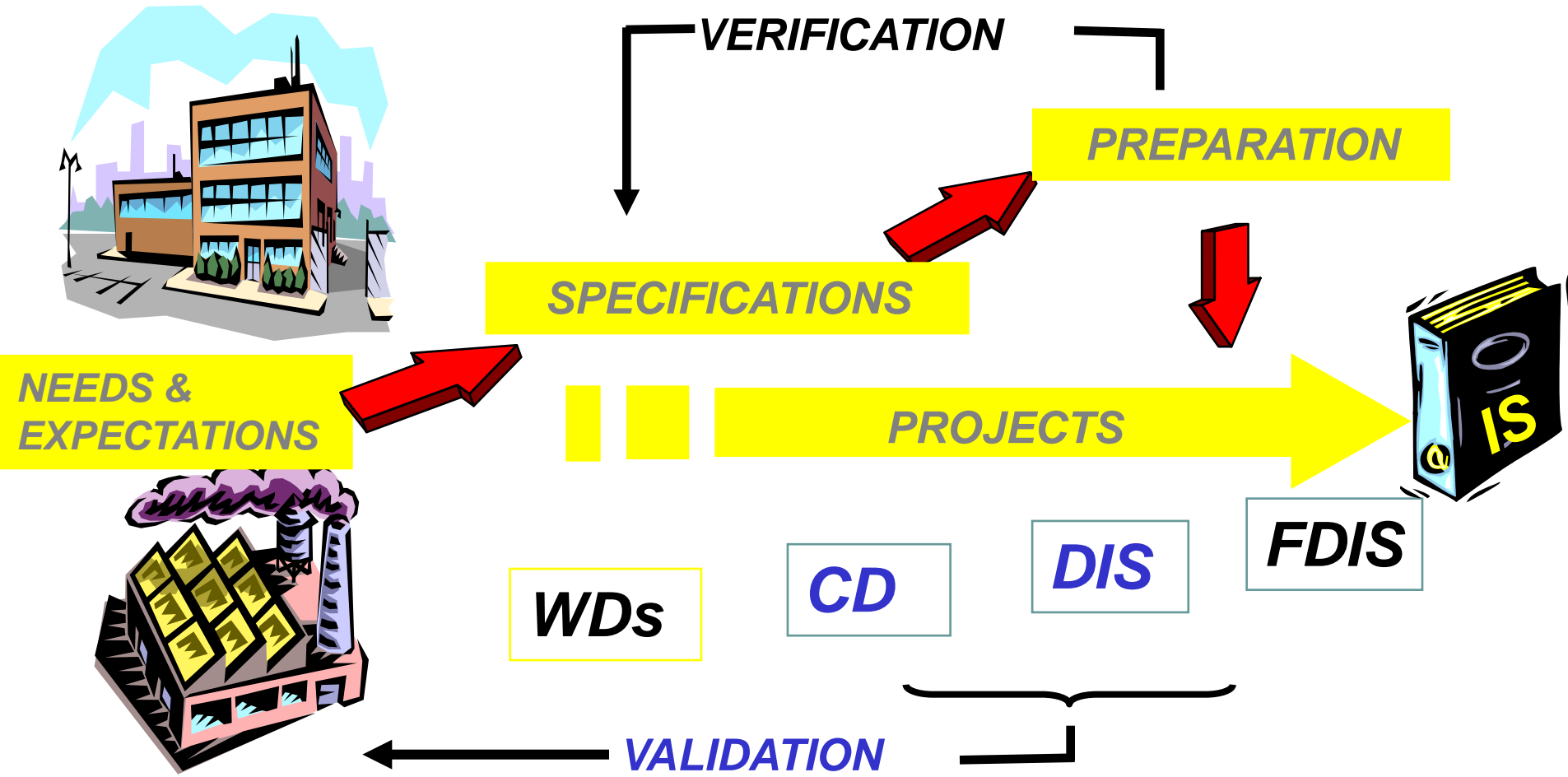
“Matrix” structure of Management System Standards





ISO 9001:2015

The standards development process





Key inputs into ISO 9001:2015

- TC176/SC2 Strategic Plan
 - Greater emphasis on organization's ability to provide conforming products – “Output Matters!”
- 12,000+ responses to online user survey
- Revision of the Quality Management Principles
- Output from the “Future Concepts” Task Group
 - Included suggestions that could not be incorporated in the 2008 revision
- Output from the ISO Joint Technical Coordination Group (“Annex SL”)



Basis for Quality Management

- 7 (Yes, now only SEVEN!!) “Quality Management Principles”
 - Customer Focus
 - Leadership
 - Engagement of people
 - Process approach
 - Improvement
 - Evidence-based decision making
 - Relationship management



Some of the topics addressed by the “Future Concepts” Task Group*

- Integration of “risk based thinking”
- More emphasis on the Quality Management Principles
- Better alignment with business management processes
- “Output matters” (Product conformity and process effectiveness)
- Knowledge management
- Life cycle management (LCM)
- Improvement and innovation
- “Time/Speed/Agility”
- Technology and Changes in IT
- Incorporation of “Quality Tools” like 6σ, QFD, benchmarking etc

* **NOTE:** Not all of these concepts were incorporated into ISO 9001:2015



Some Changes Introduced in ISO 9001:2015

- Complete reformatting to align with “Annex SL”
- “Products **and services**”
- More requirements for top (and other) management
- Need for alignment of QMS with **business processes**
- Less prescriptive in terms of documentation
- Requires greater customization - “Context”
 - **Every organization is different!**
- Identification of “interested parties”
 - **Relevant** needs and expectations of **relevant** Interested parties
 - **Customer** continues to be primary interested party
- “Actions to address risks & opportunities”
 - Not all processes have the same impact
 - Don’t all need the same level of planning and control
- Organizational knowledge

Some “deleted” requirements.....

- Elimination of the term “preventive action”
 - the concept still remains, and is actually ***reinforced throughout the standard*** (by addressing “risk”)
- Elimination of specific (prescriptive) requirements for
 - A “Quality Manual”
 - A “Management representative”



Implementation guidance

- ISO 9001 Annex A provides clarification of new structure, terminology and concepts for ISO 9001:2015
- Work is underway to develop generic implementation guidance for ISO 9001:2015
 - numbered as ISO/TS 9002
 - DTS (Draft Technical Specification) due out soon
- ISO/TC176 “Small Business Handbook” is also being updated
- Plus a lot of free guidance on the ISO website
www.iso.org



TC176/SC2/WG23 Communication and product support

- Presentation on the ISO 9001 revision (no copyright restrictions!)
- Presentation on ISO 9001 and “Risk Based Thinking”
- Paper on ISO 9001 and Risk
- Transition Planning Guidance
- Correlation matrices between ISO 9001:2008 and ISO/DIS 9001
- <http://isotc.iso.org/livelink/livelink/open/tc176SC2public>



<http://www.iso.org/iso/home.htm>

The screenshot shows the ISO website homepage. At the top left is the ISO logo. The navigation menu includes 'Standards', 'About us', 'Standards Development', 'News', and 'Store'. A search bar is located on the right side of the navigation bar. Below the navigation bar, there is a large banner image of blue water bottles with a text overlay that reads 'ISO 9001 published' and 'The much awaited 2015 edition is here. Get it now'. A yellow arrow points from this banner to the 'Popular standards' section on the right. The 'Popular standards' section lists several ISO standards: ISO 9000 Quality management, ISO 14000 Environmental management, ISO 3166 Country codes, ISO 26000 Social responsibility, ISO 50001 Energy management, ISO 31000 Risk management, ISO 22000 Food safety management, ISO 27001 Information security management, and ISO 45001 Occupational health and safety. Below the banner, there is a text block that reads 'We're ISO, the International Organization for Standardization. We develop and publish International Standards.' At the bottom of the page, there are three sections: 'Preview ISO standards', 'Looking to get certified?', and 'Common questions'. The Windows taskbar is visible at the bottom of the screenshot, showing various application icons and the system clock displaying 04:17 on 22/11/2015.

ISO - International Organi x

www.iso.org/iso/home.html

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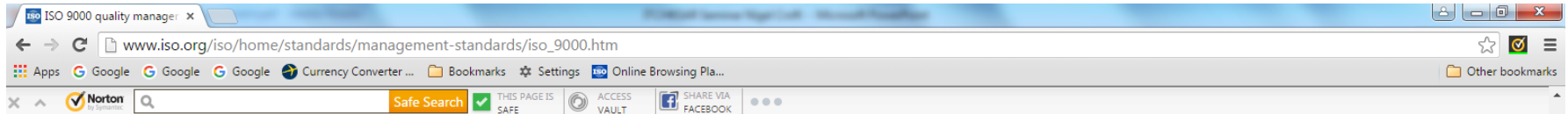
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http://www.iso.org/iso/home/standards/management-standards/iso_9000.htm



ISO 9000 - Quality management

The ISO 9000 family addresses various aspects of quality management and contains some of ISO's best known standards. The standards provide guidance and tools for companies and organizations who want to ensure that their products and services consistently meet customer's requirements, and that quality is consistently improved.

Standards in the ISO 9000 family include:

- ISO 9001:2015 - sets out the requirements of a quality management system
- ISO 9000:2015 - covers the basic concepts and language
- ISO 9004:2009 - focuses on how to make a quality management system more efficient and effective
- ISO 19011:2011 - sets out guidance on internal and external audits of quality management systems.

ISO 9001:2015

ISO 9001:2015 sets out the criteria for a quality management system and is the only standard in the family that can be certified to (although this is not a requirement). It can be used by any organization, large or small, regardless of its field of activity. In fact, there are over one million companies and organizations in over 170 countries certified to ISO 9001.

This standard is based on a number of quality management principles including a strong customer focus, the motivation and implication of top management, the process approach and continual improvement. These principles are explained in more detail in the pdf [Quality Management Principles](#). Using ISO 9001:2015 helps ensure that customers get consistent, good quality products and services, which in turn brings many business benefits.

ISO 9001 has been updated

ISO 9001 *Quality Management Systems* has recently been revised.

Learn more about the revision of ISO 9001:2015 on our [revision page](#) or watch the video below.

Get an overview of ISO 9001 in this [powerpoint presentation](#).



ISO Store

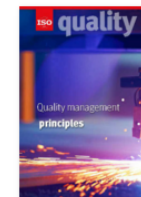
ISO 19011:2011
Guidelines for auditing management systems

ISO 9000:2015
Quality management systems -- Fundamentals and vocabulary

ISO 9001:2015
Quality management systems -- Requirements

ISO 9004:2009
Managing for the sustained success of an organization -- A quality management approach

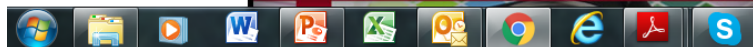
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Quality management principles

Information about the quality management principles used in standards such as ISO 9001.

Download pdf





http://www.iso.org/iso/home/standards/management-standards/iso_9000/iso9001_revision.htm

Standards > Management system standards > ISO 9000 > ISO 9001 Revision

ISO 9001 Quality Management Systems Revision

ISO 9001 Quality Management Systems, the world's leading quality management standard, has recently been revised.

Why was ISO 9001 revised?

All ISO standards are reviewed every five years to establish if a revision is required to keep it current and relevant for the marketplace. TISO 9001:2015 is designed to respond to the latest trends and be compatible with other management systems such as ISO 14001.

The timeline is below. Learn more about the process of [standard development](#).

ISO 9001 revision timeline:

- Proposal Stage: May-June 2012
- Preparatory Stage: June-October 2012
- Committee Stage (CD): June-September 2013
- Enquiry Stage (DIS): May-October 2014
- Approval Stage (DIS) CURRENT: July 2015
- Expected publication: September 2015

Meet the experts behind the revision

Watch the Google hangout where members of the ISO subcommittee responsible for ISO 9001 talk to us about the newly revised version.

See all [Quality management standards](#)

Useful links

Read the latest news about the ISO 9001 revision

[ISO 9001 Technical Committee website](#)



<http://isotc.iso.org/livelink/livelink/open/tc176SC2public>

Committee 01. Public info x

isotc.iso.org/livelink/livelink/open/tc176SC2public

ISO TC/176/SC2 Home Page

ISO's Technical Committee no.176, Sub-committee no.2 (ISO/TC 176/SC 2) is responsible for the development of the ISO 9001 and ISO 9004 International Standards as well as other International Standards and documents in the ISO 9000 Family.

ISO/TC 176/SC 2 has been granted the following "scope" for its activities by ISO/TC 176:

"Standardization in the field of generic quality systems and quality methodologies, including standards which provide guidance on the selection, application and use of these standards."

The Secretariat of ISO/TC 176/SC 2 is provided by the [British Standards Institution \(BSI\)](#).
The Chairman is Dr Nigel Croft from the UK ([about the chairman](#))
The Secretary is Mr Charles Corrie, charles.corrie@bsigroup.com.

This web site contains the following sections:

1. [Revision of ISO 9001](#)
2. [Advice and information on ISO 9001 and ISO 9004](#)
3. [In search of sustainable success](#)
4. [Interpretations of ISO 9001](#)
5. [Links to the ISO 9001 Auditing Practices Group and Accreditation Auditing Practices Group web sites](#)
6. [Information on ISO](#)
7. [Information about ISO/TC 176/SC2 and about ISO/TC 176](#)

Please either click on the above links or scroll down the page to access the different sections.

1. Revision of ISO 9001

A link to a brief description of ISO/TC 176/SC2's current activities ([here](#))

News on the ISO 9001 revision ([here](#))

A presentation on the ISO 9001 revision ([here](#))

A presentation on ISO 9001 and Risk Based Thinking ([here](#))

A paper on ISO 9001 and Risk ([here](#))

Transition to ISO 9001:2015

- ISO 9001:2015 published 15th Sept 2015
 - Same date as ISO 14001:2015
- ISO/TC176, ISO/CASCO and IAF have approved a ***3-year transition period***
- All organizations are strongly encouraged to start the transition as soon as possible
 - Aim is to avoid “peak” of audits to the new standard near end of transition period
 - Avoid overload of CB resources
- Detailed guidance in IAF ID9:2015 (www.iaf.nu)



Conclusions

- ISO is aligning its portfolio of management system standards
 - Aim is to facilitate integration
- ISO 9001 has undergone a “major revision”
 - Published Sept 15th 2015
 - Significant changes in structure and clause sequence
 - “Process Approach + PDCA + Risk-based thinking”
 - Some new requirements
- Find out more by consulting www.iso.org
- Start preparing for the transition NOW!

THANK YOU!



nhc@tcaglobal.org