

ISO 9001 & ISO 14001 Revisions – what will change, and why?

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- Any opinions expressed by the presenter are personal viewpoints, and no formal endorsement of ISO, IAF, ISO/TC176 or ISO/CASCO should be implied
- Information about the revision of ISO 9001 and ISO 14001 is not final and should not be used for making changes to existing quality management systems.

Presentation Outline.....

- Background
- ISO Directives “Annex SL” – the need for harmonization of management system standards
- ISO 9001:2015 – what to expect
- ISO 14001:2015 – what to expect
- Transition arrangements

BACKGROUND

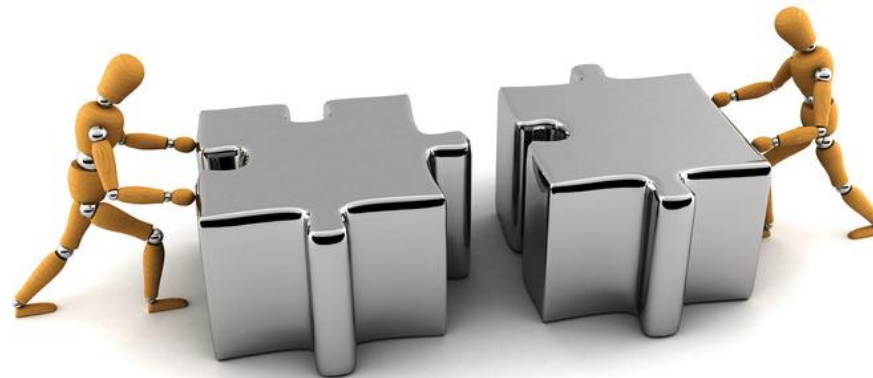


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ISO Mission

- 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 Committees TC 176 and TC207



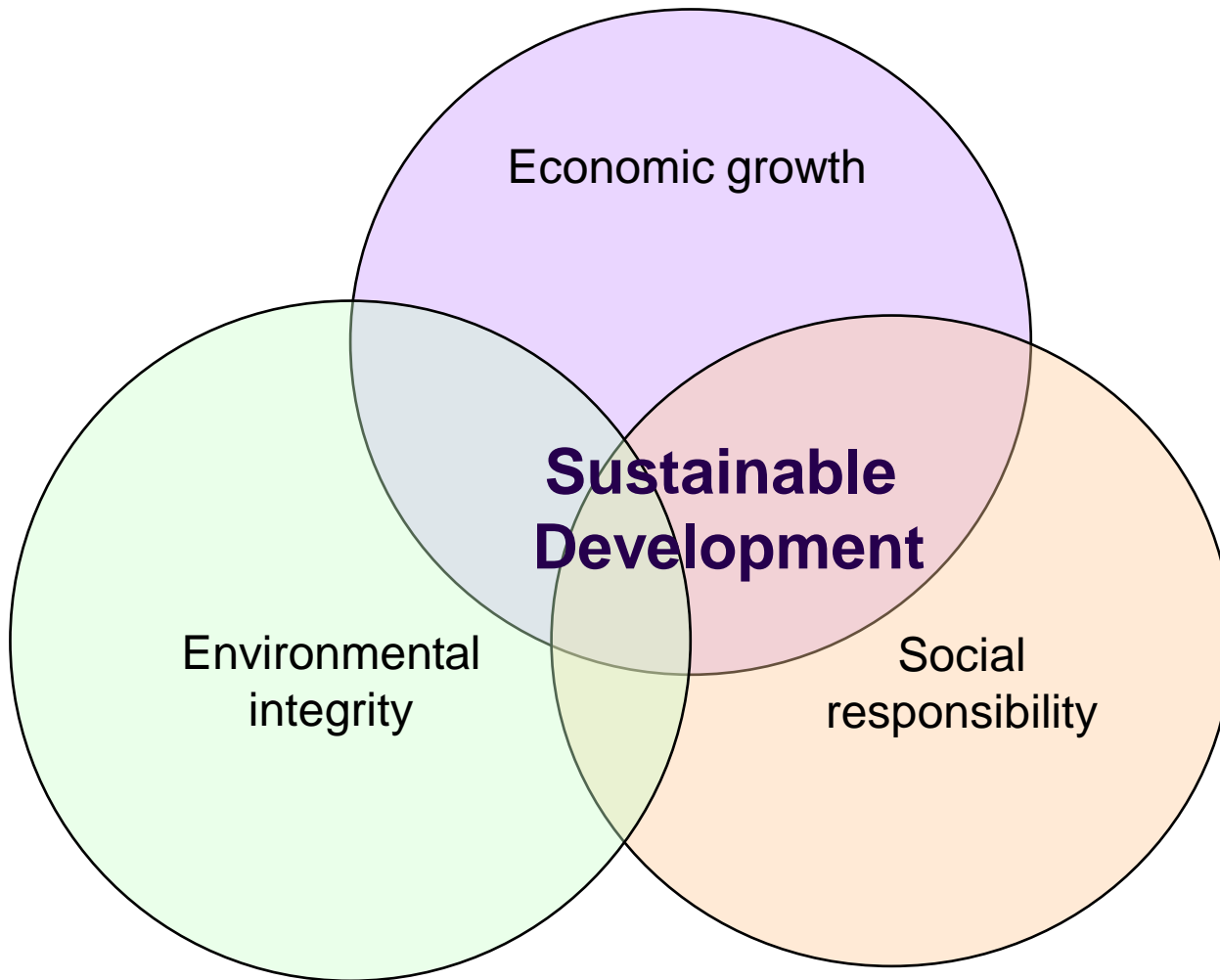
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- “ISO” = International Organization for Standardization
 - Confederation of National Standards Bodies
 - Based in Geneva
- Standards development work is done by Technical Committees comprising experts nominated by their national standards body or 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
- “TC 207” = Technical Committee Number 207 for Environmental Management
 - “TC 176/SC 1” is the subcommittee responsible for ISO 14001

DREAMING OF A SUSTAINABLE FUTURE!



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..... **BUT SIMPLY DREAMING IS NOT ENOUGH!!!**



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Dr W. Edwards Deming

“How could there be life without aims and hopes? Everyone has aims, hopes, plans.

But a goal that lies beyond the means of accomplishment will lead to discouragement, frustration, demoralization.

In other words, there must be a method to achieve an aim.....***BY WHAT METHOD??***”





“The Method”

- Management system
 - “system to establish policy and objectives *and to achieve those objectives*” (ISO 9000:2005 definition)

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

- ISO 9001 – “Consistent, conforming products”
- ISO 14001 – “Prevention of pollution”
- OHSAS 18001 – “Safe working conditions”
- ISO 50001 – “Efficient energy usage”
- ISO 22000 – “Safe food”
- etc

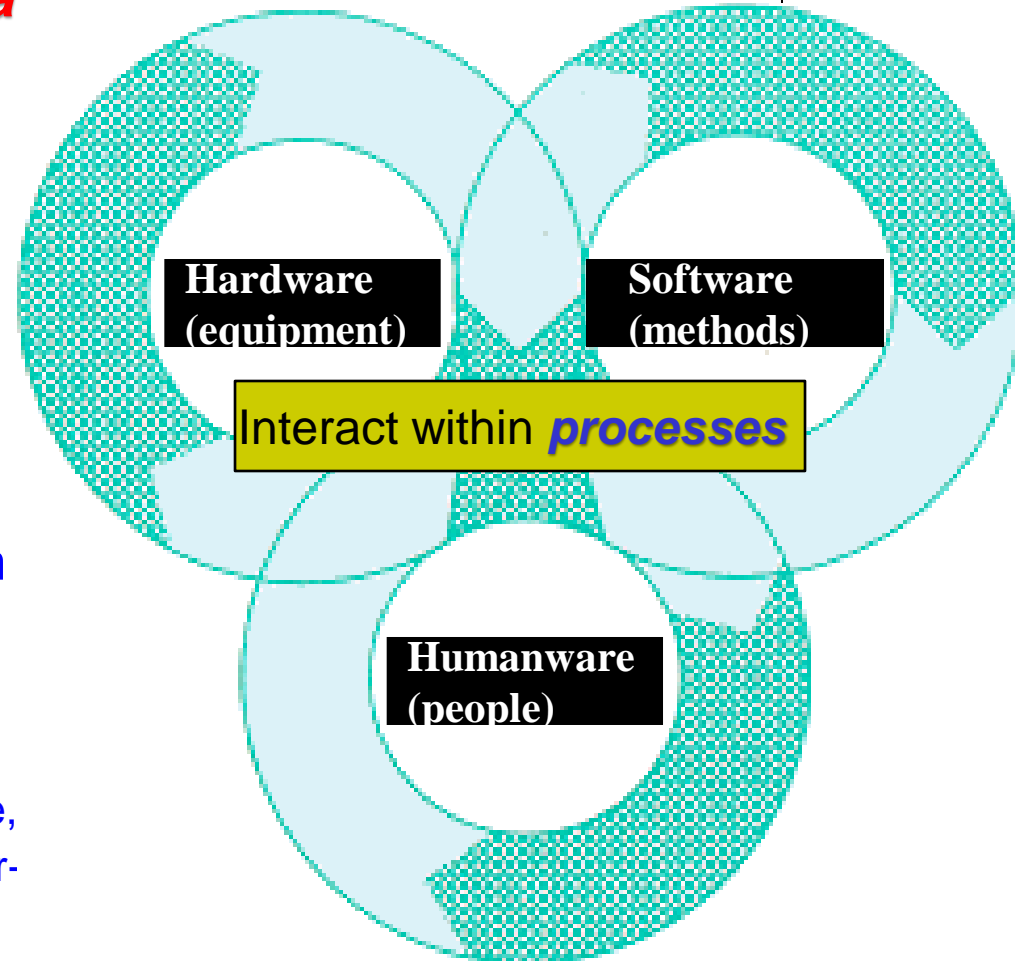
A “management system”



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

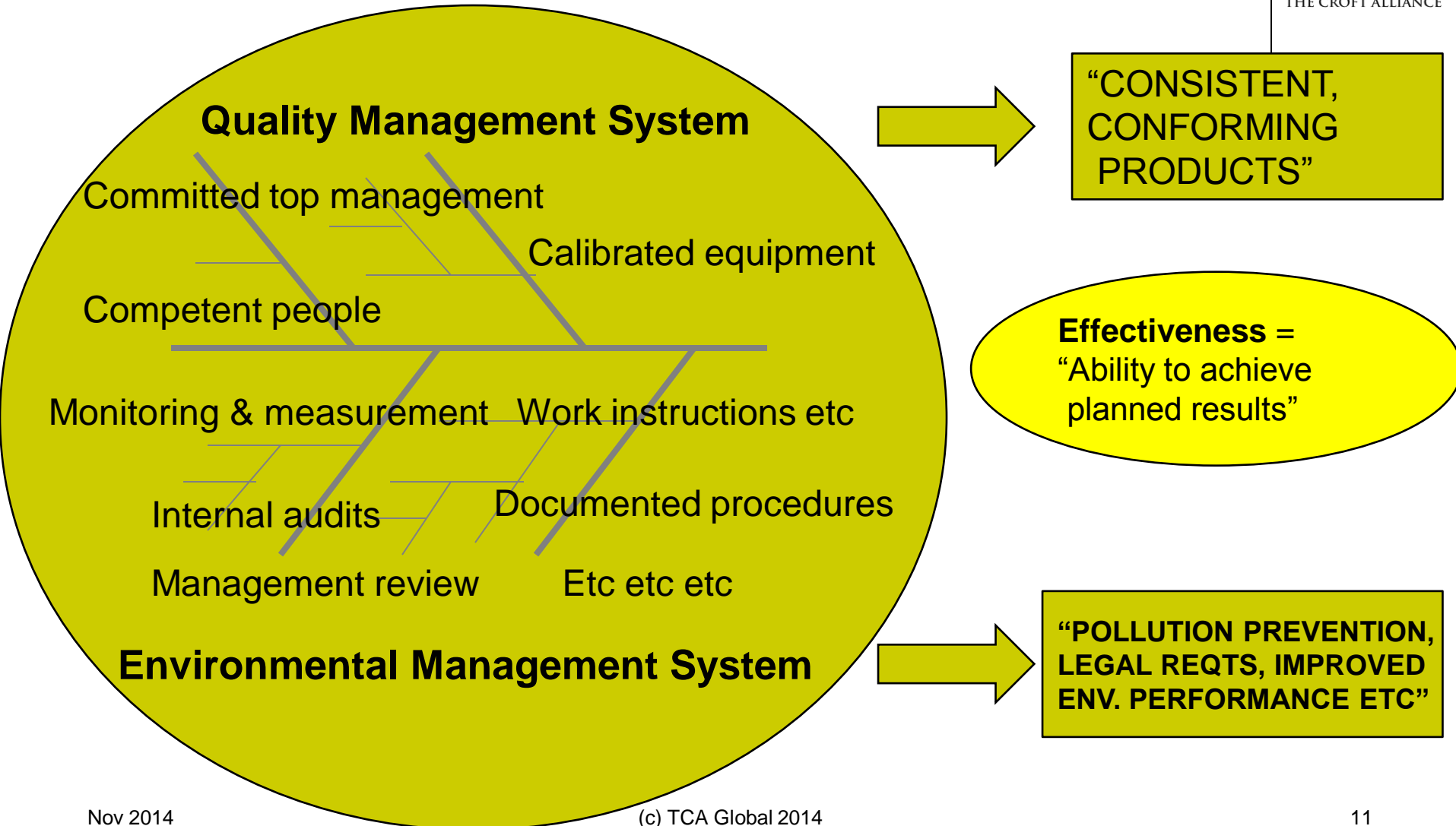
IMPORTANT:

- 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





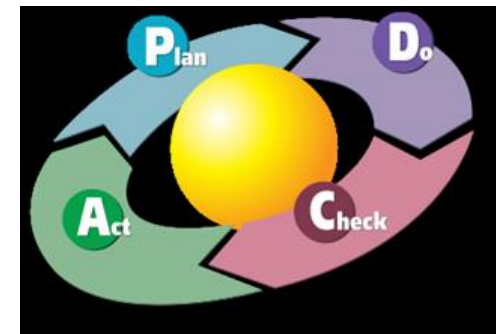
“Cause and effect”





3 core concepts*

- 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”**

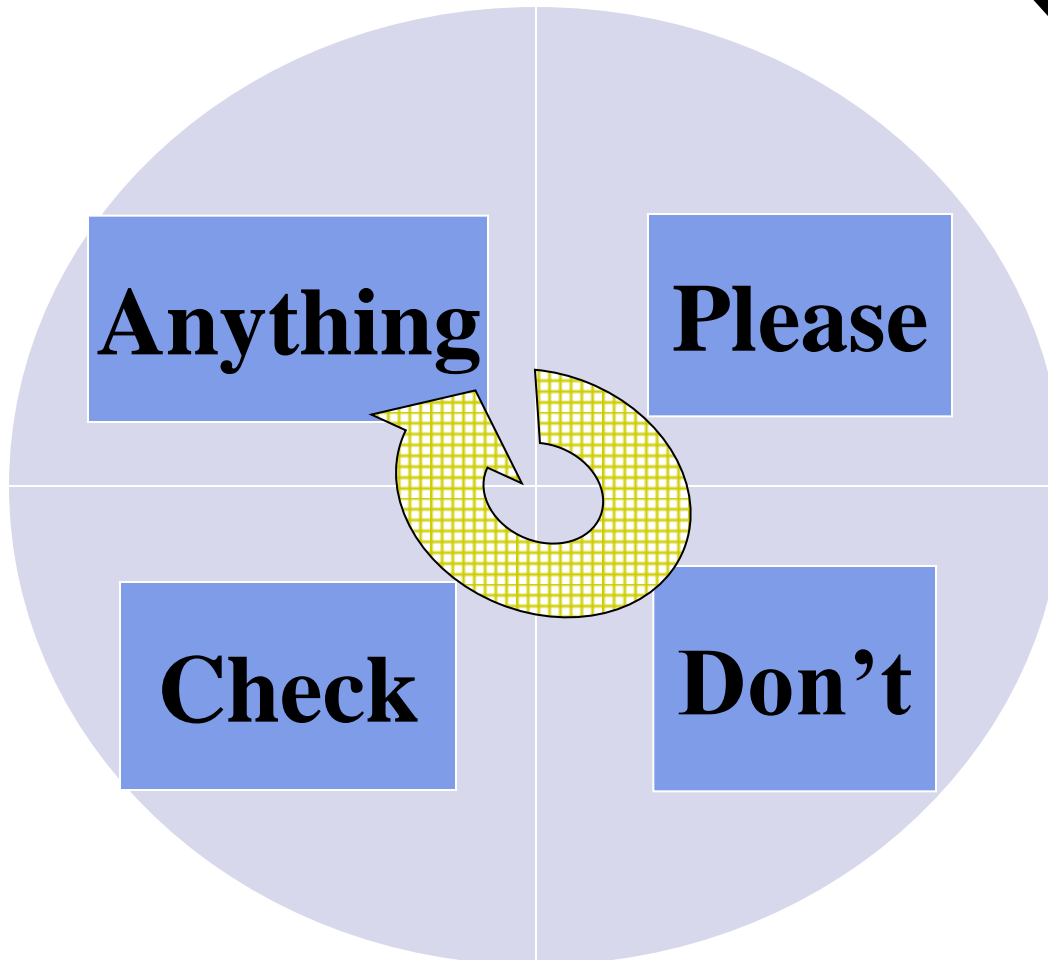


* = Nigel Croft's understanding

The “P-D-C-A” Cycle??



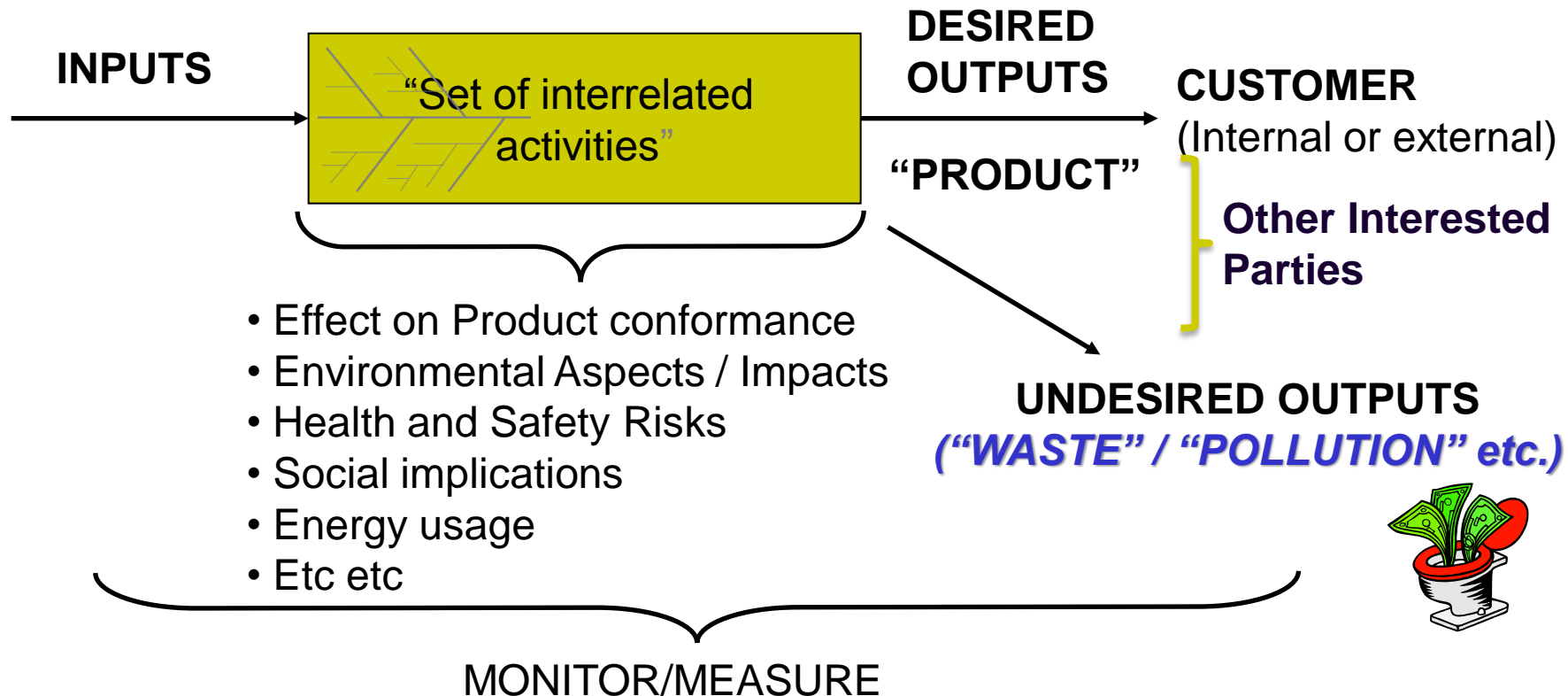
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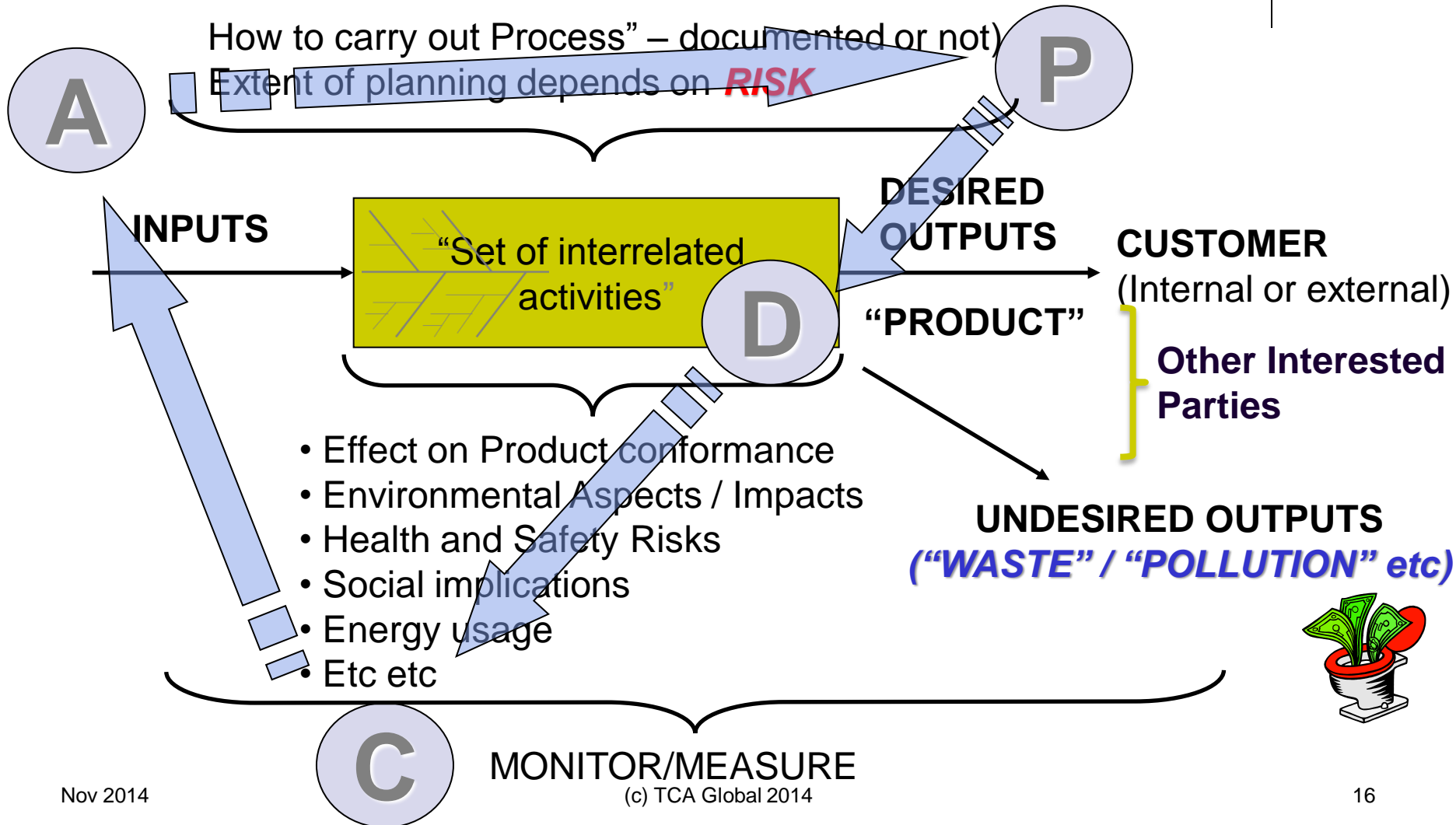
Generic Process

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

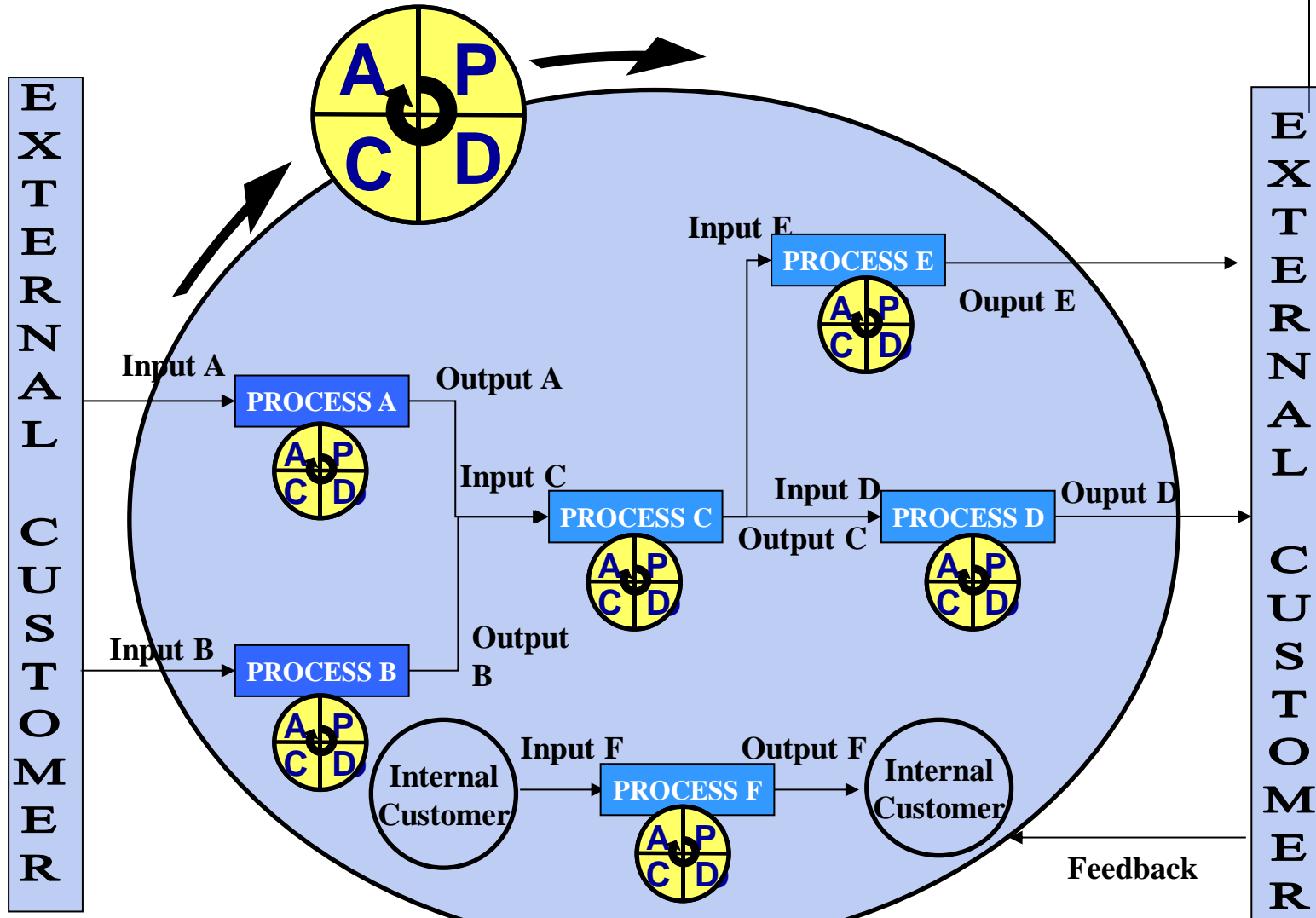




Generic Process



System of processes



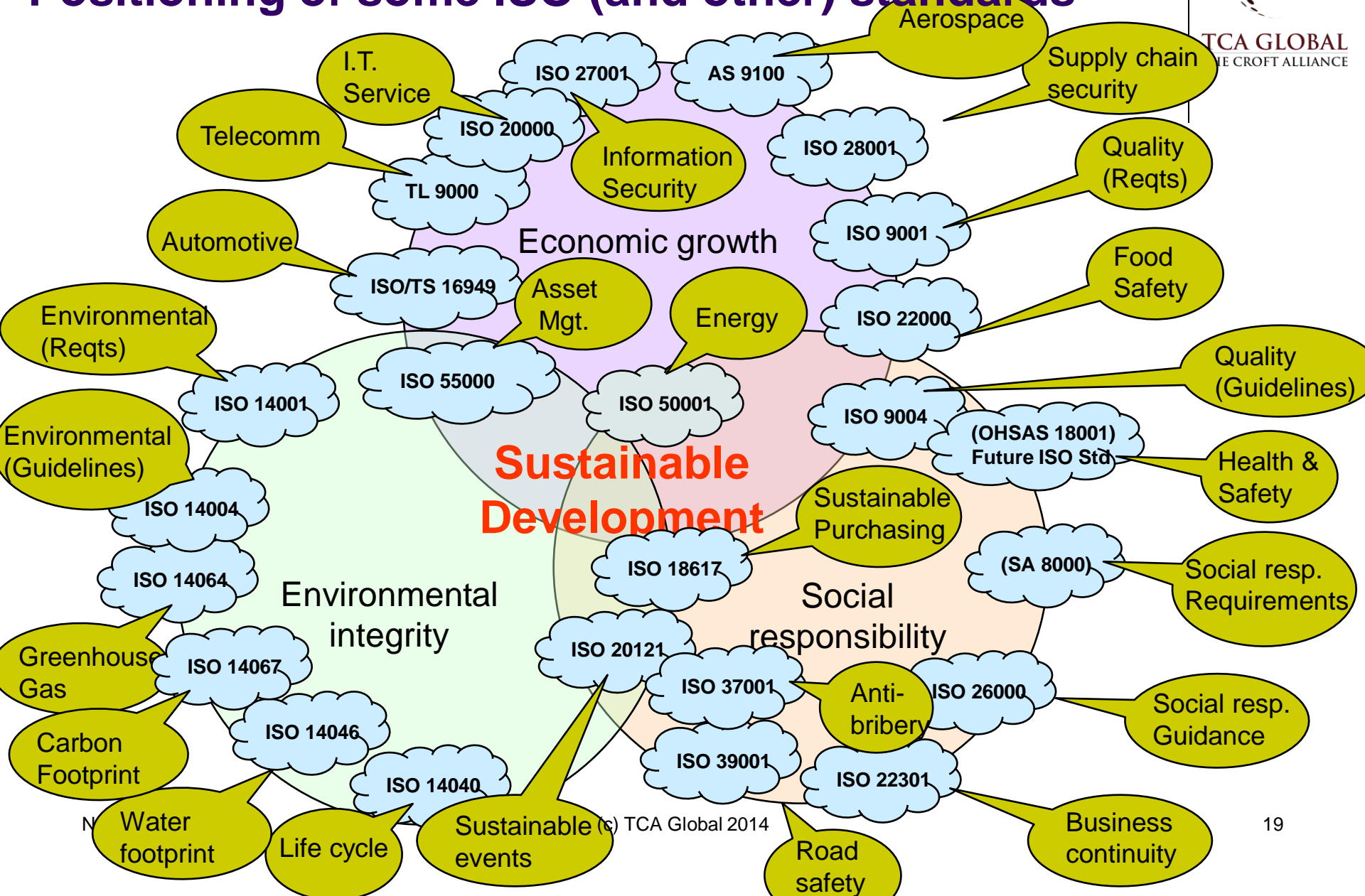
Harmonization of management system standards



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Positioning of some ISO (and other) standards



Need for 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 Part 1:2012 “Annex SL”



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- Incorporates the recommendations of the JTCCG 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

ISO 9001:2015 – What to expect



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Overall Scenario of ISO/TC176

- Development of generic quality management system standards that have broad application:
 - all market sectors
 - both 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!



ISO/TC176/SC2 Vision

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



* ISO 9001, ISO 9004, and other guidance documents

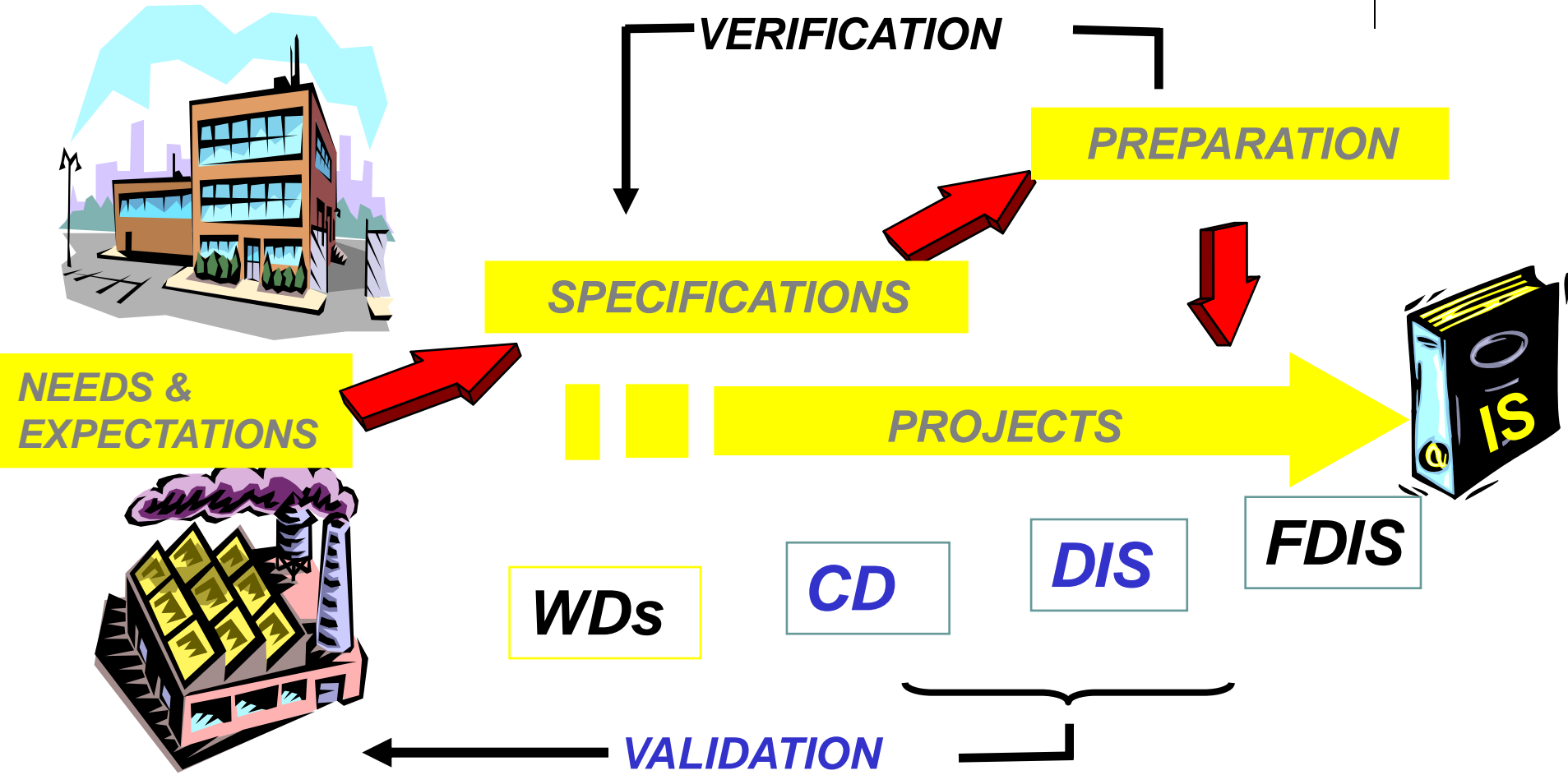


ISO/TC176/SC2 Mission

- 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.

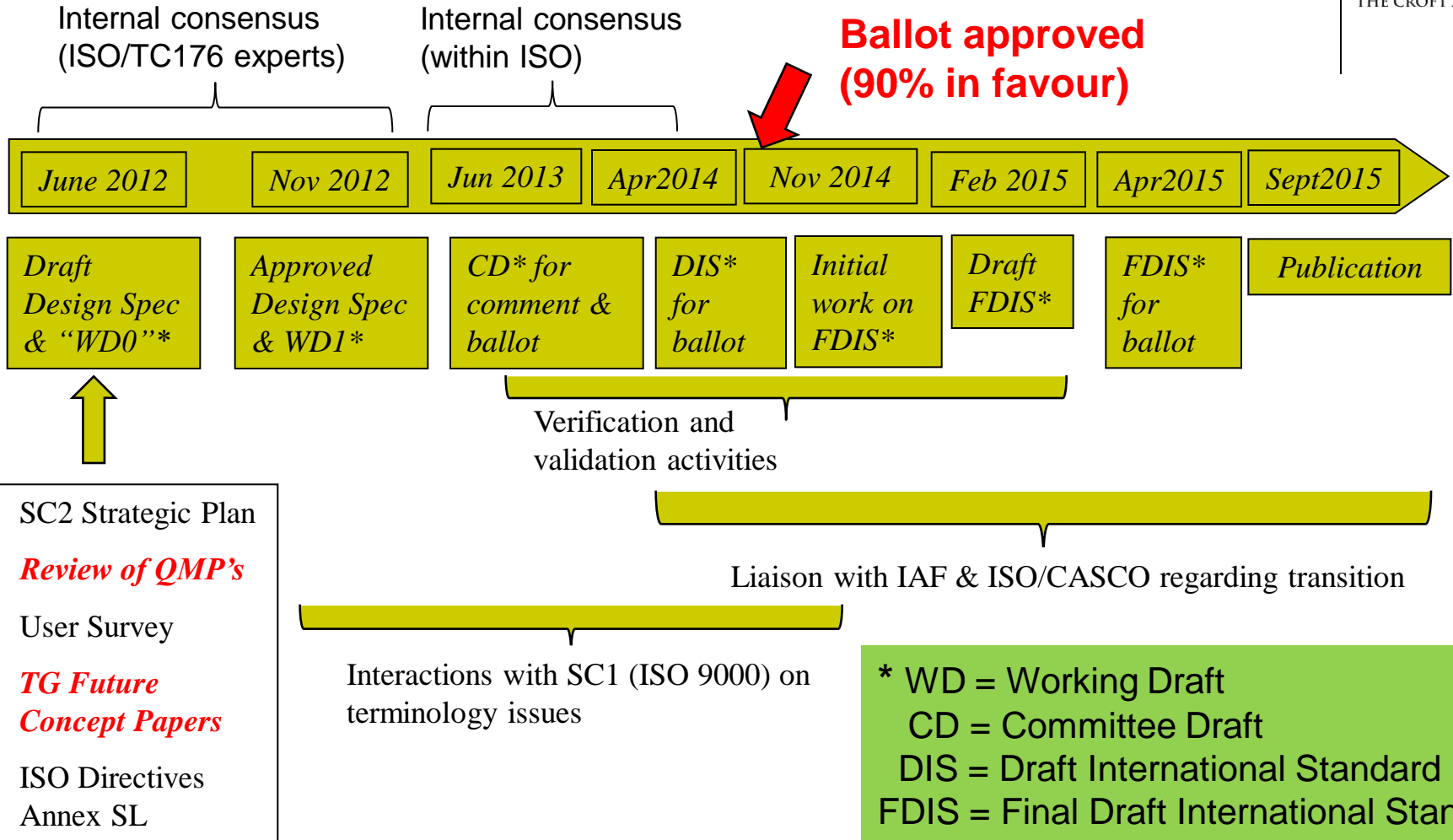


The standards development process





High-Level Timing for ISO 9001:2015



The Global Challenges for Quality Management Systems



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- Increased customer expectations for confidence in products and services
- Increasing use of QMS standards for global trade
- Increasing use of ISO 9001 by various industry sectors
- Credibility of 3rd party certification
- Drive for greater efficiency (lean initiatives)
- Increased sophistication of quality management tools
- Increasing regulatory emphasis on public health and safety (e.g., food; medical devices)
- Multiple management systems standards, programs and schemes.



Key objectives for “ISO 9001:2015”

Extracts from ISO 9001:2015 “Design Specification”:

- Provide stable core set of requirements for next 10 years or so
- ***Maintain current focus on effective process management to produce desired outcomes***
- Take account of changes in QMS practices and technology since the last major revision (in 2000)
- ***Apply Annex SL of ISO Directives to enhance compatibility & alignment with other ISO management system standards***
- Facilitate effective organizational implementation and effective conformity assessment by 1st, 2nd and 3rd parties
- ***Simplified language and writing styles to aid understanding and consistent interpretations of requirements.***

Key inputs into “ISO 9001:2015”

- TC176/SC2 Strategic Plan
 - Greater emphasis on organization’s ability to provide conforming products – “Output Matters!”
 - Greater clarity and simplicity of language for better implementation
- 12,000+ responses to online user survey
- Revision of the 8 Quality Management Principles
- Output from the “Future Concepts” Task Group
 - Includes suggestions that could not be incorporated in the 2008 revision
- Output from the ISO Joint Technical Coordination Group (now published in the ISO Directives)

Review of Quality Management Principles



- Joint SC1/SC2 Task Group
 - Led by Prof. Y. Iizuka (Japan – Deming prizewinner!)
 - High level “strategic thinkers”
- Aim is to review existing 8 QMP’s
 - Are they still relevant?
 - Any modifications needed?
 - Any new principles to be added?
 - Ethics?
 - Organizational agility?
 - Others?
- Work is now complete.
 - New QMPs will only be published when ISO 9000:2015 and ISO 9001:2015 are published (to avoid confusing people!)



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*



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- 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 are being incorporated into ISO 9001:2015

Some changes (Based on “DIS” of ISO 9001)



- Complete reformatting to align with “Annex SL”
- “Products and services” instead of “product”
- More requirements for top (and other) management
- “External provision of products and services” instead of “purchasing” – includes outsourced processes
- “Documented information” instead of “Documented procedures and records”



Some new requirements.....

- New Clause 4.1 - “Context of the Organization”
 - What are the external and internal factors?
- Identification of “interested parties”
 - **Relevant** needs and expectations of the **relevant** Interested parties?
 - **Customer** continues to be the primary (but not the only!) interested party
- “Actions to address risks & opportunities”
 - May change at FDIS to “Opportunities and risks”
 - Guidance document available on www.iso.org
- Organizational knowledge
- “Improving products and services to meet known and predicted requirements”

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”

Some “Post-DIS” changes



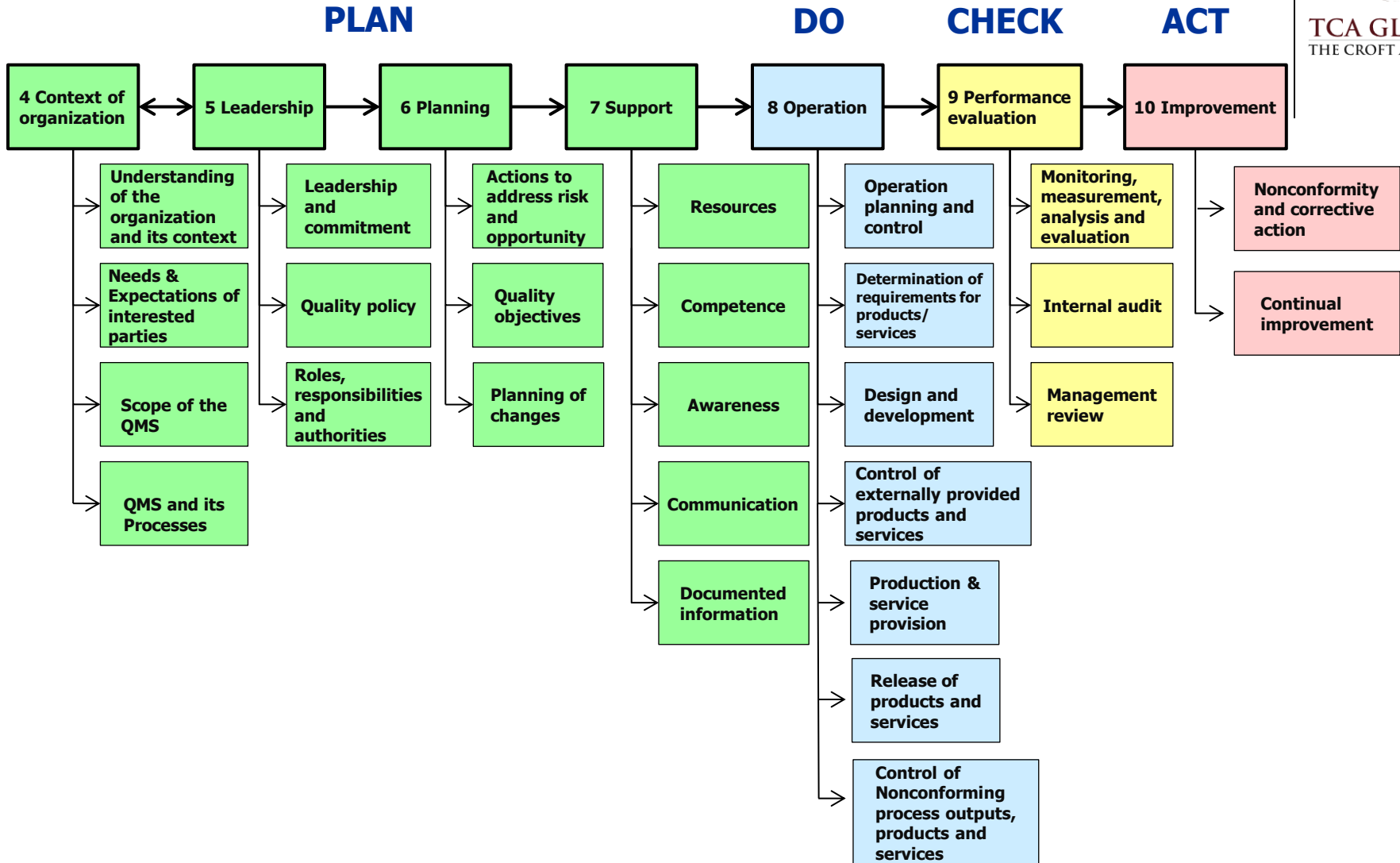
- Terms and definitions will probably go out of ISO 9001*
- ISO 9000 will again become a “normative reference”*
- A lot of discussion about how to address the question of “innovation”

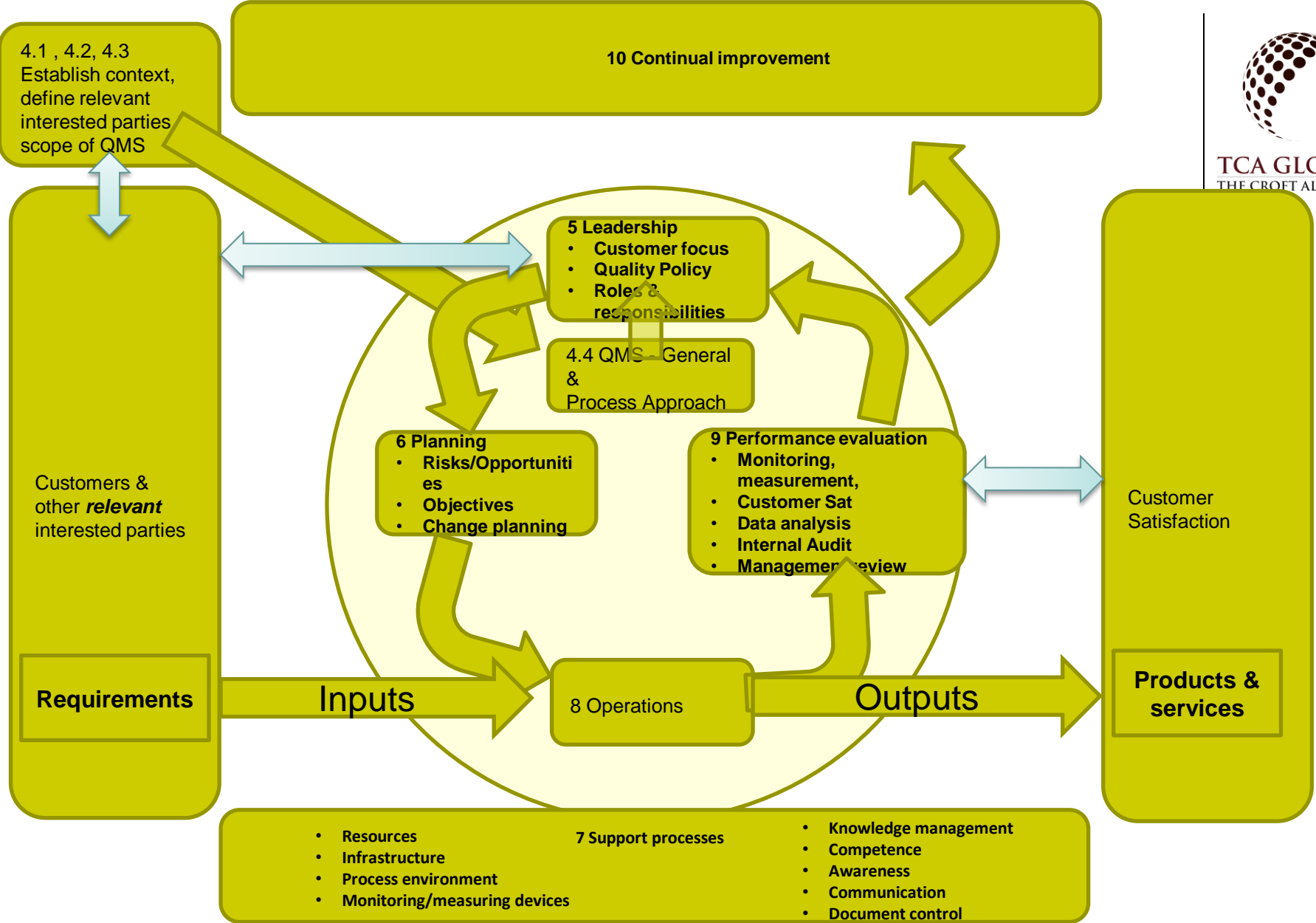
* Subject to a formal ballot

Structure of ISO 9001:2015



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What next?

- Work carried out by WG24 Task Groups in Galway will be reviewed for consistency etc
 - Electronic working over next 3 months
- Validation work continues (WG24/TG5)
 - Results will feed into next full WG24 meeting (Feb 2015)
- “FDIS” scheduled for release in March 2015
- Work is underway to develop generic implementation guidance for ISO 9001:2015 (and/or revision of “Small Business Handbook”)

14001:2015 – What to expect



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Some of the challenges.....

- Environmental concerns arising from:
 - pollution;
 - excessive demands on resources;
 - degradation of eco-systems
 - bio-diversity issues
 - management of waste
 - climate change
 - increasing world population
- Greater expectations from society for transparent, responsible sustainable development.
- Increasingly rigorous legislation
- Value-chain and life-cycle concepts

Key Objectives for ISO 14001:2014



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- Consider the final report of the ISO/TC 207 SC 1 "Future Challenges for EMS" Study Group
- Ensure maintenance and improvement of the basic principles of ISO 14001: 2004, with retention and improvement of its existing requirements.
- Base on “Annex SL structure”

EMS Future Challenges Study Group



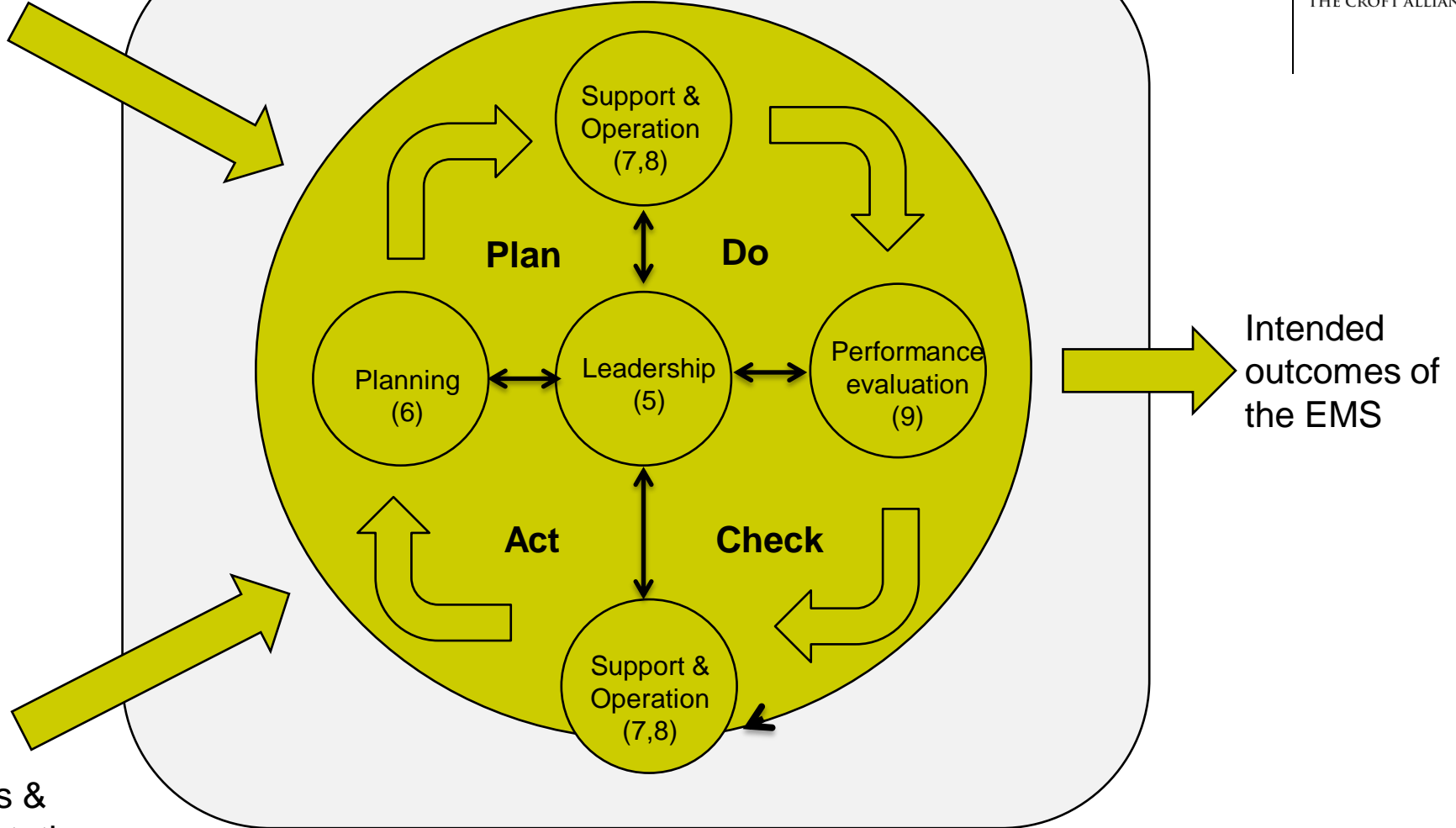
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- Emphasize that an organization should retain responsibility to align its ISO 14001 processes with its environmental and business priorities
- Strengthen focus on subjects such as:
 - Transparency and accountability
 - Value chain influence and responsibility
- Express environmental management more clearly as contributing to sustainable development, one of the key pillars of social responsibility
- Broaden and clarify the concept of “Prevention of pollution”
- Strengthen performance evaluation as part of ISO 14001
- Emphasize the strategic considerations, benefits and opportunities of EMS
- Strengthen strategic relationship between EMS and core business including interactions with stakeholders (including clients and suppliers)
- Address life cycle thinking and value chain perspectives more clearly in the identification and evaluation of environmental aspects



Internal &
External
Issues (4.1)

Scope of the EMS (4.3 / 4.4)



Intended
outcomes of
the EMS

Needs &
Expectations
of Interested
Parties (4.2)



Some key changes

- Use of “Annex SL” leads to similar changes as for ISO 9001
 - Context of the organization
 - Interested parties
 - “Risks & Opportunities” (and threats)
 - Reinforced requirements for leadership
 - Need to integrate EMS into business operations
 - “Documented information”



Some new requirements

- Now need to address “processes and their interactions”
- “Compliance obligations”
 - Quite a lot of ongoing discussion
- Policy to include “other specific commitment(s) relevant to the context of the organization”, e.g:
 - sustainable resource use
 - climate change mitigation and adaptation
 - protection of biodiversity and ecosystems
- Environmental aspects to include life-cycle perspective



What next?

- Ballot on DIS closed on Nov 28th (just a few hours ago!)
- Results expected soon
 - Likely to be approved
 - Likely to have significant number of comments
- TC207/SC1 will meet Feb 2015 to address comments
- FDIS scheduled for mid-2015
- Likely publication Sept 2015



Collaboration between TC176 & TC207 to further align ISO 9001:2015 & ISO 14001:2015

TABLE 1 - REQUIREMENTS (CLAUSES 4 TO 10)

ISO DIS 14001	ISO DIS 9001
<p>4.1 Understanding the organization and its context</p> <p>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 environmental management system. Those issues include environmental conditions capable of affecting or being affected by the organization.</p> <p><i>(See Annex 4.1 for comparable 14001 guidance)</i></p> <p><i>(See Annex 4.1 for comparable 14001 guidance)</i></p>	<p>4.1 Understanding the organization and its context</p> <p>The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.</p> <p>The organization shall monitor and review the information about these external and internal issues.</p> <p>Note 1 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.</p> <p>Note 2 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.</p>
<p>4.2 Understanding the needs and expectations of interested parties</p> <p>The organization shall determine:</p> <ul style="list-style-type: none"> - the interested parties that are relevant to the environmental management system; and - the relevant needs and expectations (i.e. requirements) of these interested parties, and - which of these needs and expectations become compliance obligations 	<p>4.2 Understanding the needs and expectations of interested parties</p> <p>Due to their impact or potential impact on the organisation's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:</p> <ul style="list-style-type: none"> a) the interested parties that are relevant to the quality management system; and b) the requirements of these interested parties that are relevant to the quality management system. <p>The organization shall monitor and review the information about these interested parties and their relevant requirements.</p>

Transition to ISO 9001:2015 and ISO 14001:2015



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- Both are scheduled for publication Sept 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

Conclusions

- ISO is aligning its portfolio of management system standards
 - Aim is to facilitate integration
- ISO 9001 and ISO 14001 are both undergoing a “major revision”
 - Both at DIS stage – scheduled publication mid-late 2015
 - Significant changes in structure and clause sequence
 - “Process Approach + PDCA + Risk-based thinking”
 - Some new requirements
- Stay tuned to what’s happening via www.iso.org
- Start preparing for the transition NOW!

THANK YOU!



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