



Understanding, Knowledge, and Awareness of ISO 9001:2015

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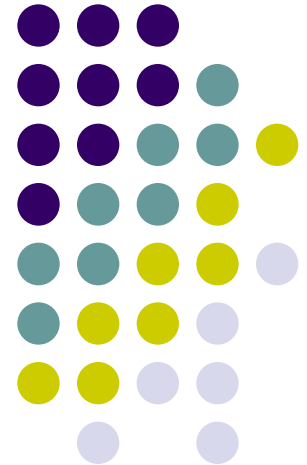
E-Mail: nhc@tcaglobal.org

- Currently holds senior management positions and serves as non-executive board member of a number of commercial and non-profit organizations in Europe, the Middle East, Asia and the Americas
- Born and educated in the UK, but spent much of his professional life in Brazil. Currently holds dual citizenship (Brazil / UK)
- Member of the Brazilian Delegation to ISO/TC176 from 1995 to 2010, and was Task Group Leader for the Introduction and Transition planning for ISO 9001:2000.
- Served from 1999 to 2010 as the ISO/TC176 Liaison to ISO/CASCO and the IAF, and was Founding Co-Chair of the ISO/IAF “ISO 9000 Advisory Group”.
- Holds a First Class Honours Degree in Natural Sciences from Cambridge University in the UK, and PhD in Materials Science from the University of Sheffield.

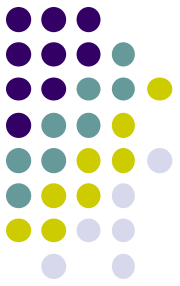
NOTE: Dr Croft is donating his professional fee for this Webinar to SOFT – Support Organization for Trisomy (<http://trisomy.org>)

Understanding, Knowledge, and Awareness of ISO 9001:2015

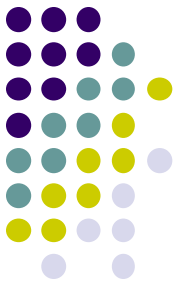
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Disclaimer



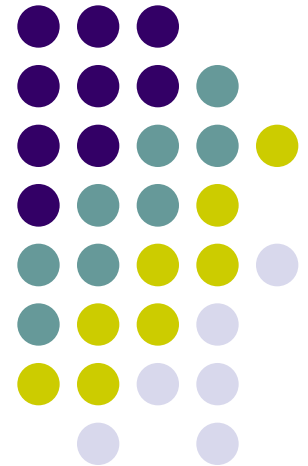
- Any opinions expressed by the presenter are personal viewpoints, and no formal endorsement of ISO, IAF, ISO/TC176 or ISO/CASCO should be implied
- Information about the revision of ISO 9001 is not final and should not be used for making changes to existing quality management systems.



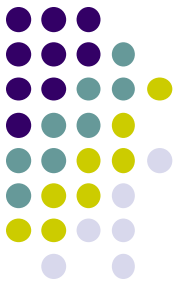
Presentation Outline.....

- Harmonization of ISO's management system standards
- Background and inputs to the revision of ISO 9001
- ISO 9001:2015 – what to expect
 - New structure
 - New requirements
 - Unchanged requirements
 - Deleted requirements
- Transition arrangements

BACKGROUND



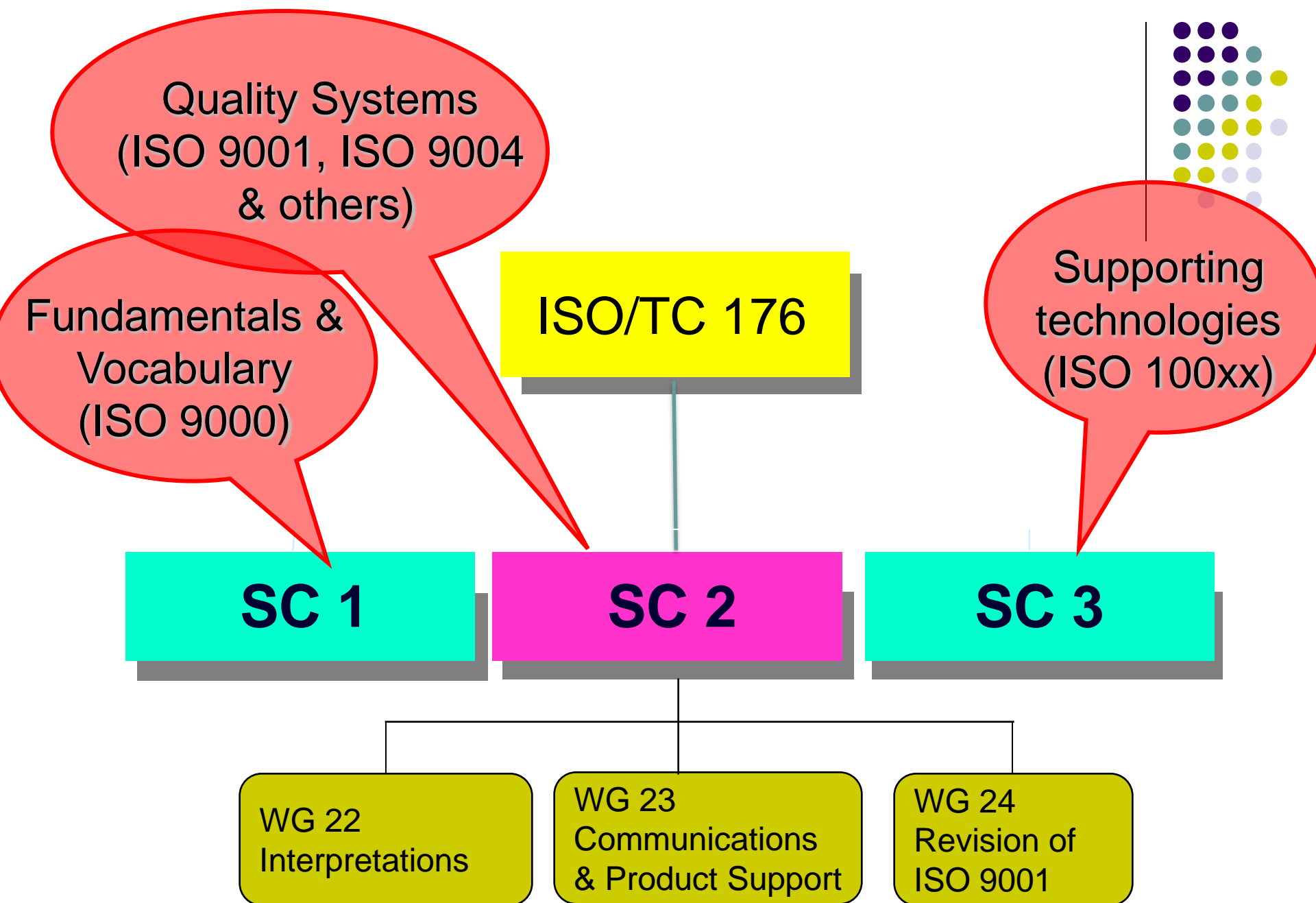
Overall Scenario of ISO/TC176



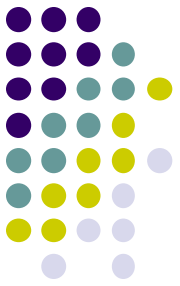
- Development of generic quality management system standards that have broad application:
 - all market sectors
 - both private and public organizations
- Approx. 1.1 million certifications to ISO 9001 worldwide

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

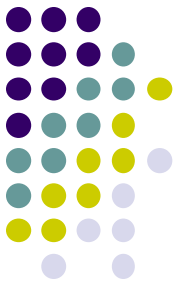


“SC2’s products* are ***recognized and respected worldwide***, and ***used by organizations as an integral component of sustainable development***”



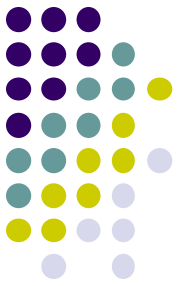
* ISO 9001, ISO 9004, and other guidance documents

ISO/TC176/SC2 Mission

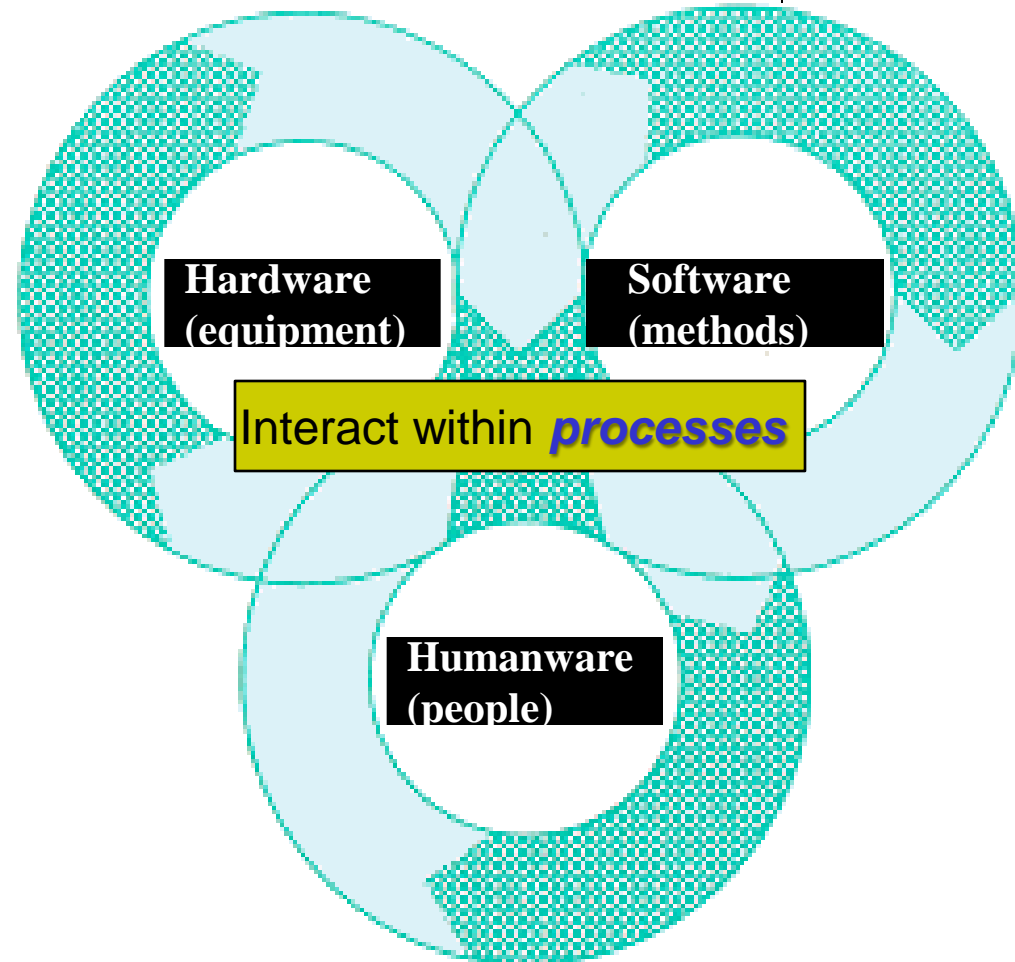


- To *develop, maintain and support a portfolio of products that enable organizations to improve their performance* and to benefit from the implementation of a robust quality management system.
- *To establish generic quality management system requirements that provide the foundations to build confidence 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.

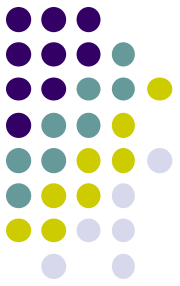
What is a “management system”?



- Formal definition.....
“set of *interrelated or interacting elements* of an organization *to establish policies and objectives*, and *processes to achieve those objectives*”
- In other words:
System should be **results focused**
A “documented system” – NOT a “system of documents”

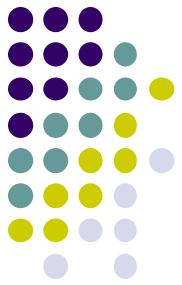


“Expected results” from management systems:



- 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.

“Cause and effect”



Quality Management System

Committed top management

Calibrated equipment

Competent people

Monitoring & measurement

Work instructions etc

Internal audits

Documented procedures

Management review

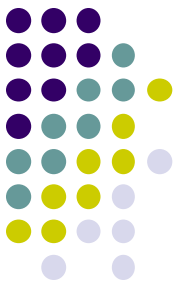
Etc etc etc

Effectiveness =
“Ability to achieve
planned results”



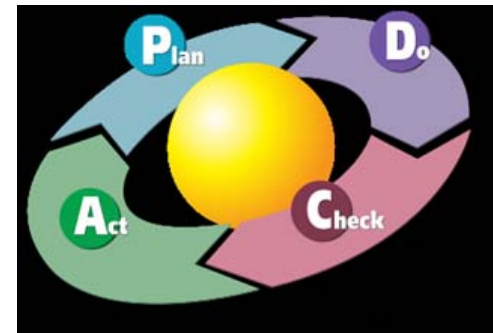
“CONSISTENT,
CONFORMING
PRODUCT”

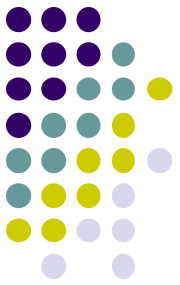
Efficiency =
“Achieve planned results
with minimum resources”
(\sum Outputs / \sum Inputs)



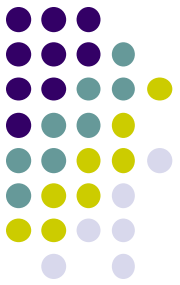
3 core concepts.....

- 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”**

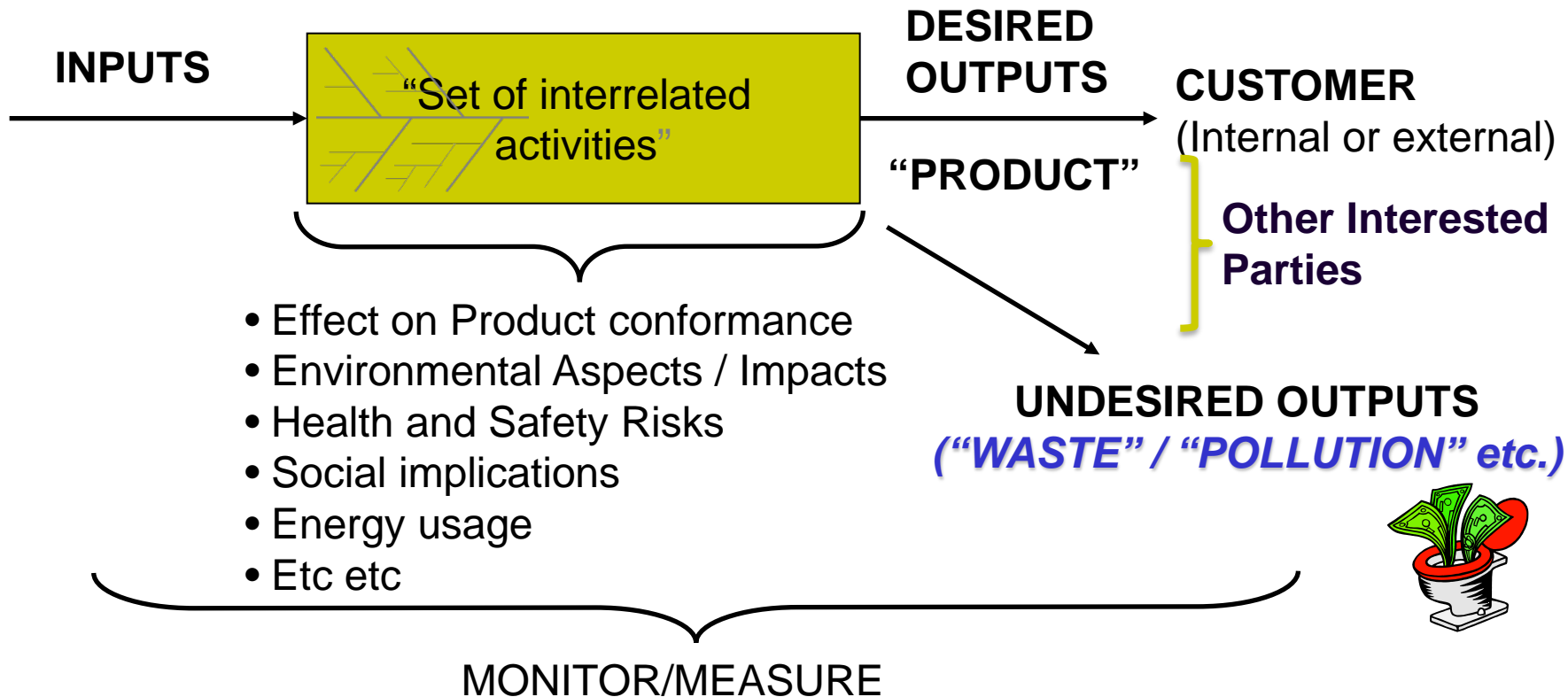




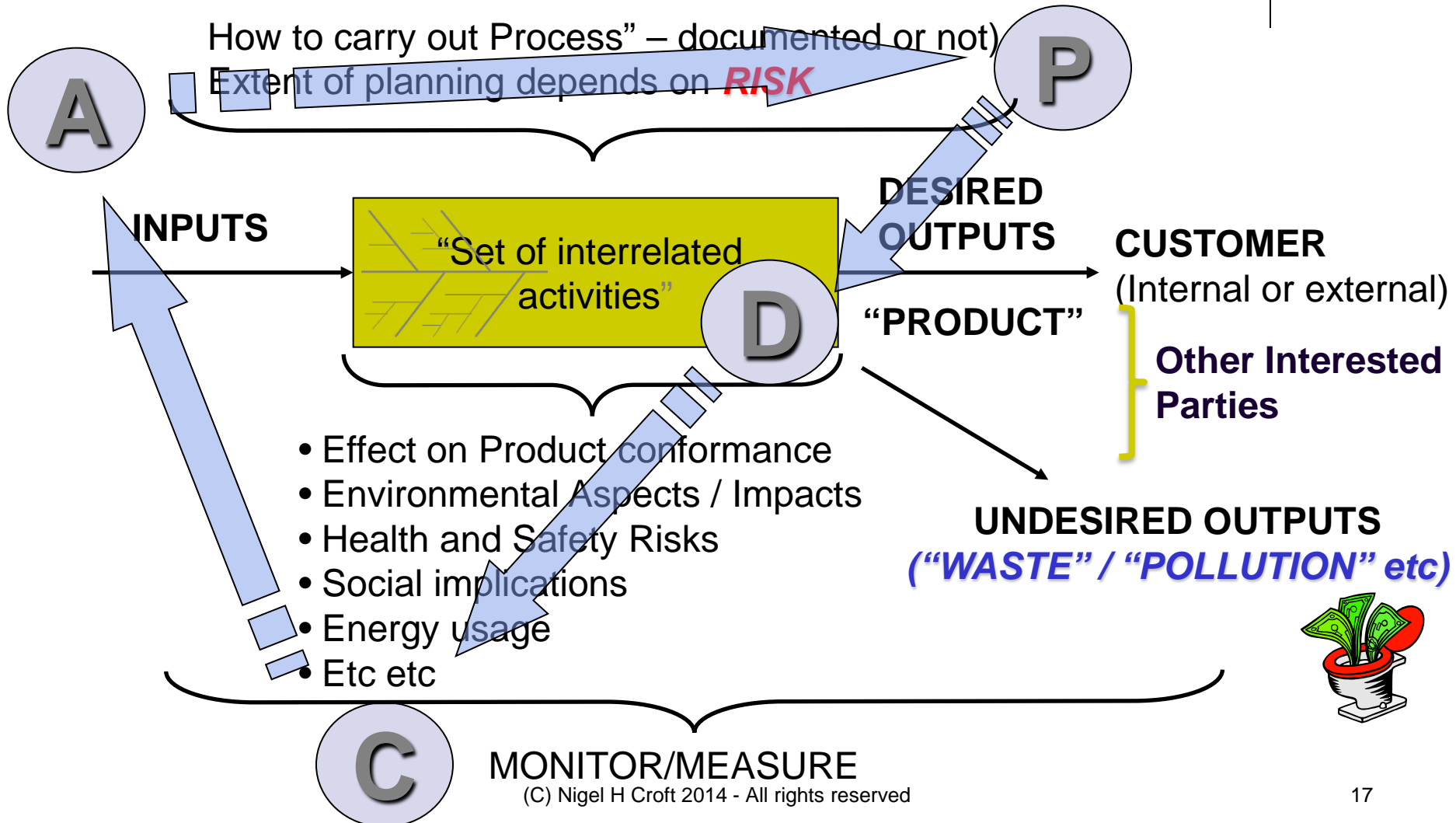
Generic Process



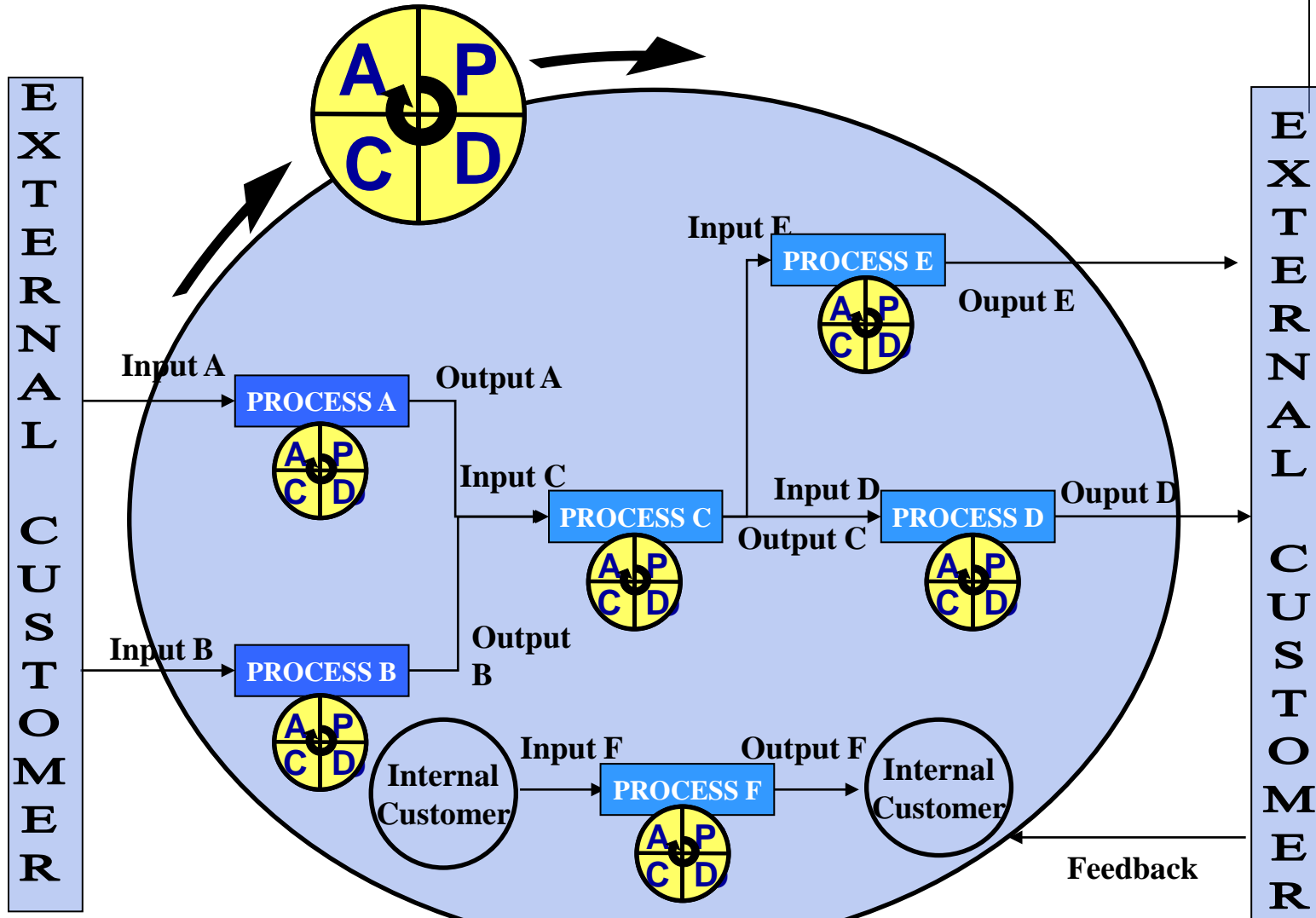
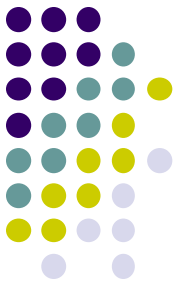
How to carry out Process” – documented or not)
Extent of planning depends on **RISK**



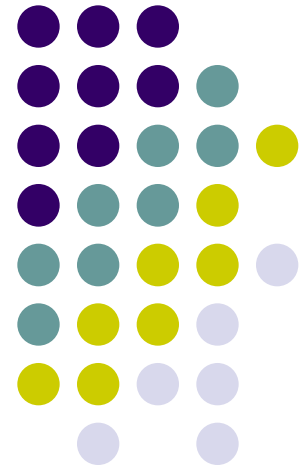
Generic Process



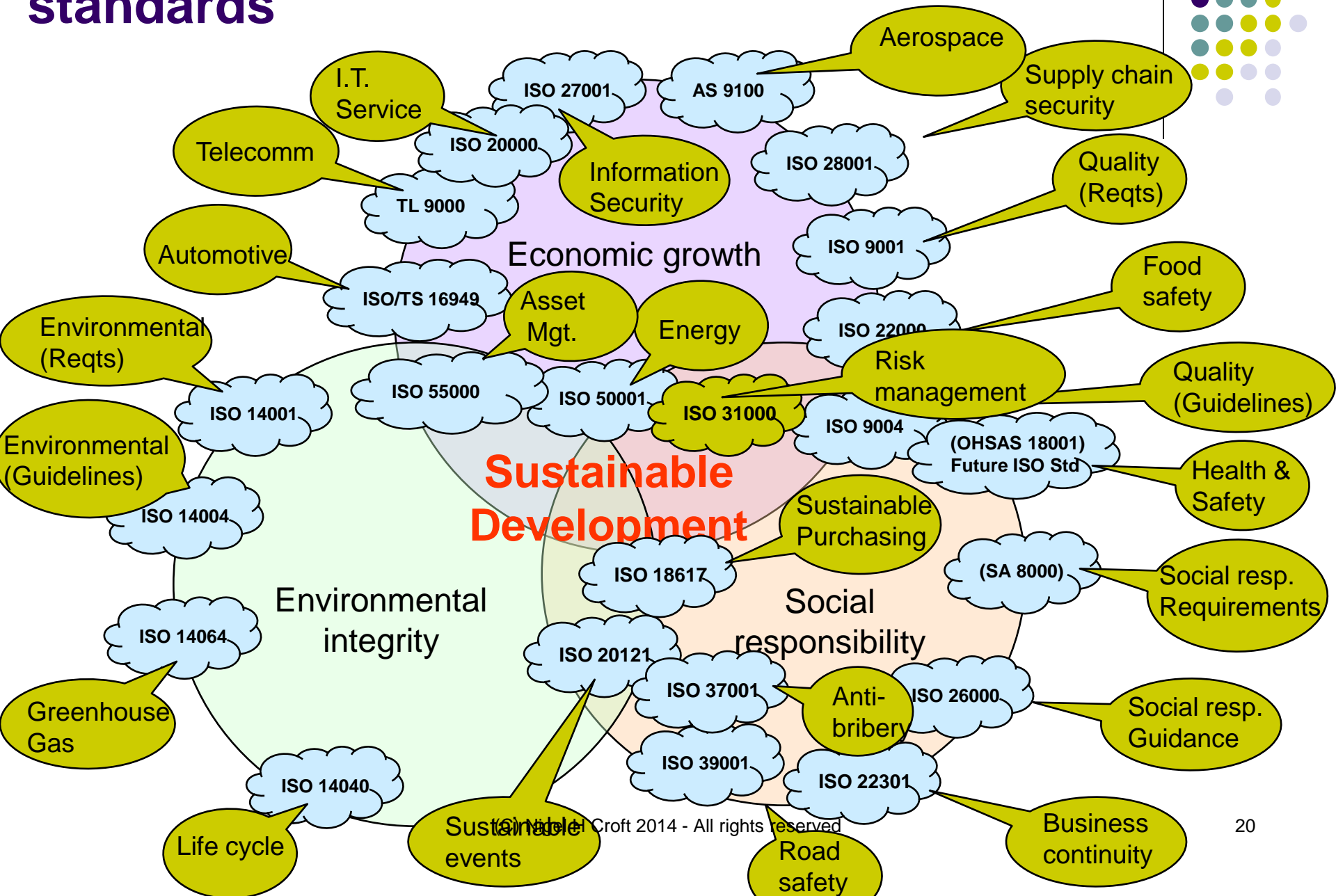
System of processes



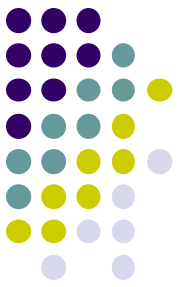
Harmonization of management system standards



Positioning of some ISO (and other) standards

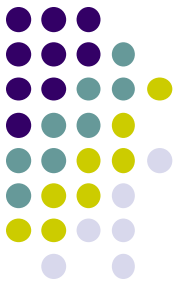


Need for Alignment of management system standards!



- 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”



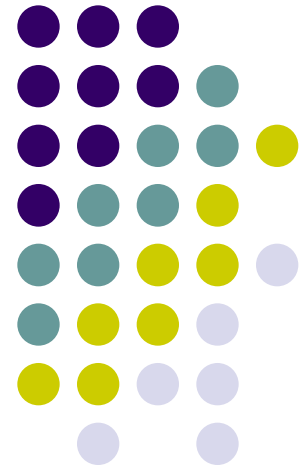
- Incorporates the recommendations of the JTCG work
- Defines the common structure and format for all new ISO management system standards ***and revisions to existing standards***
- Common text (approx 30% or more of each standard will be identical text)
- Significant impact on future revisions of ISO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

“Annex SL” High Level Structure



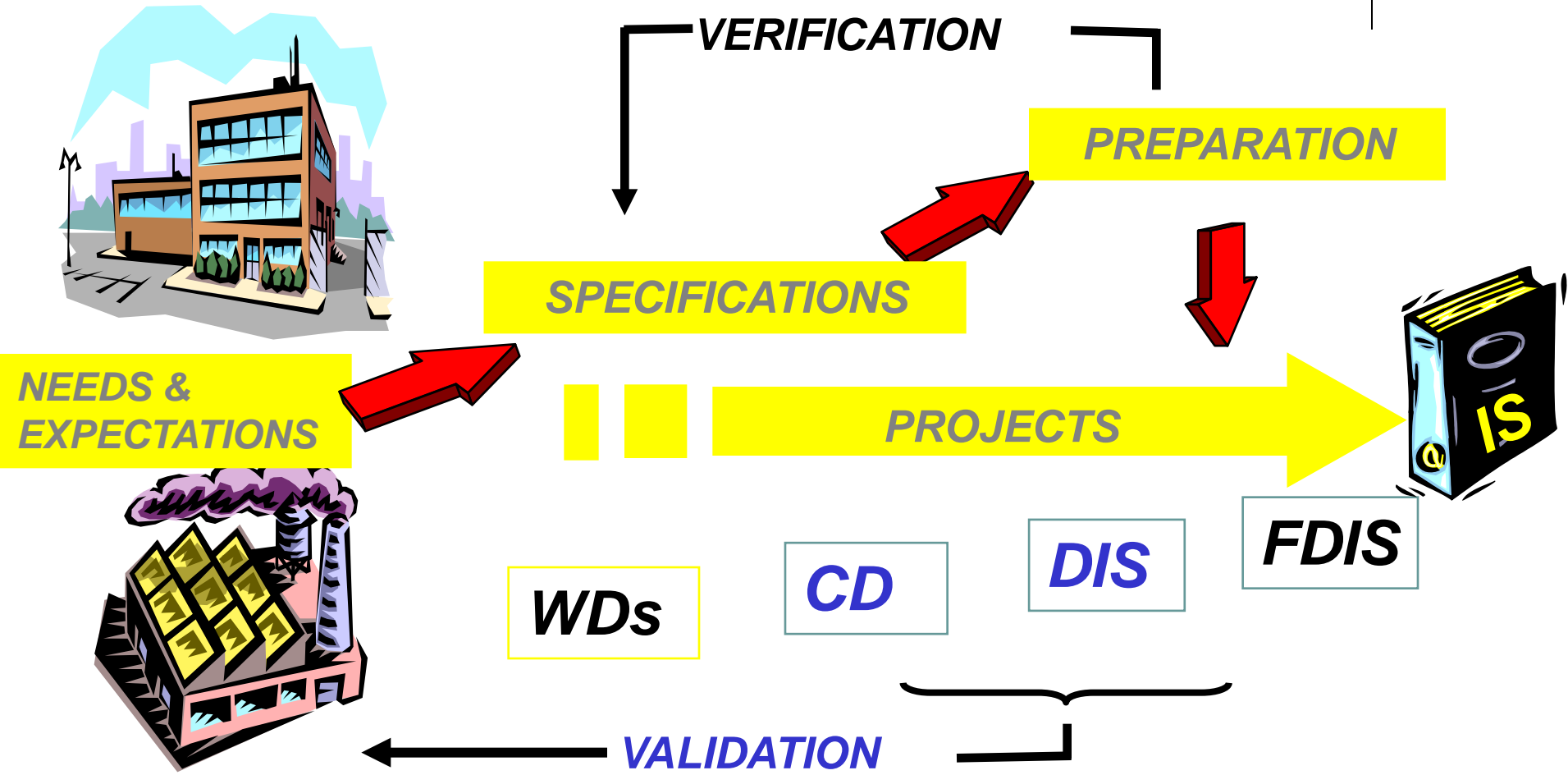
1. **Scope**
2. **Normative references**
3. **Terms and definitions**
4. **Context of the organization**
 - *Understanding the organization and its context*
 - *Needs and expectations of interested parties*
 - Determining the scope
 - Management System
5. **Leadership**
 - *Leadership and commitment*
 - 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

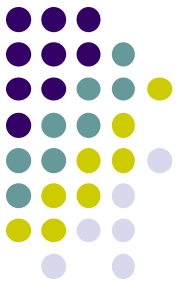
ISO 9001:2015 – What to expect



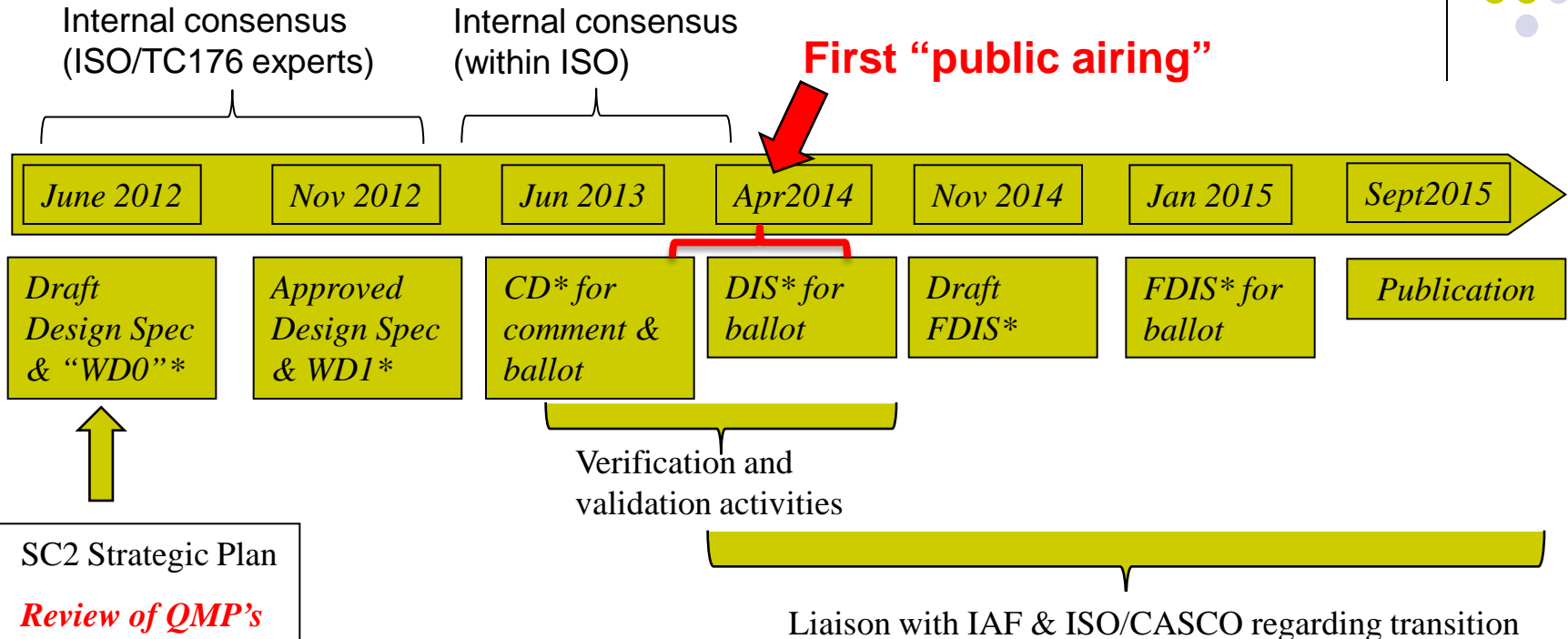


The standards development process



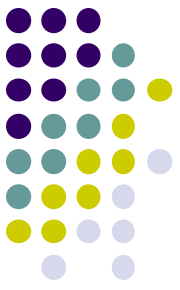


High-Level Timing for ISO 9001:2015



- SC2 Strategic Plan
- **Review of QMP's**
- User Survey
- **TG Future Concept Papers**
- ISO Directives Annex SL

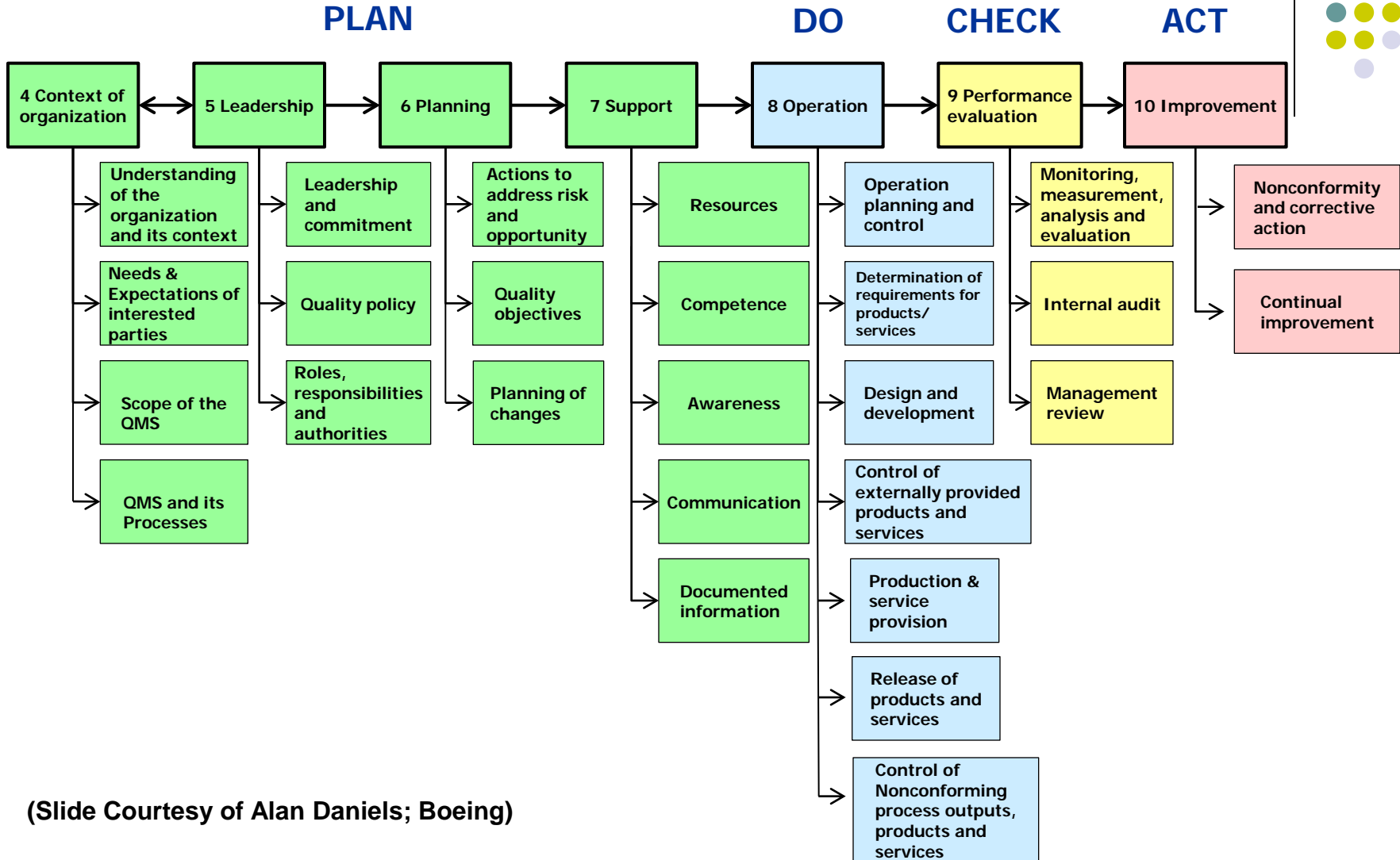
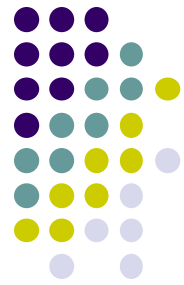
* WD = Working Draft
CD = Committee Draft
DIS = Draft International Standard
FDIS = Final Draft International Standard



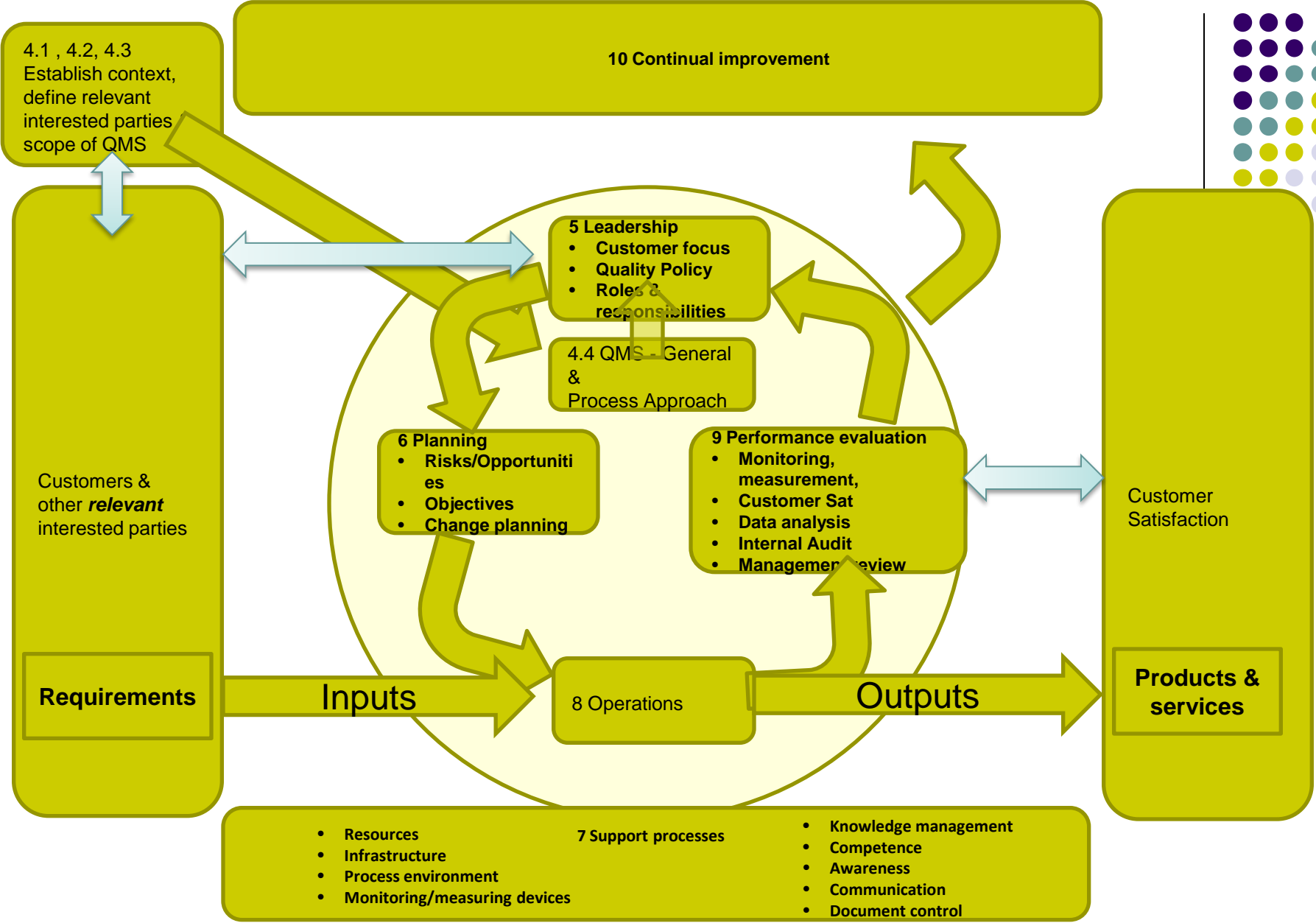
Some key changes.....

- Complete reformatting to align with “Annex SL”
- “Products and services” instead of “product”
- More emphasis on addressing “risks & opportunities”
- Elimination of the term “preventive action”
 - the concept still remains, and is actually reinforced throughout the standard (by addressing “risk”)
- “External provision of products and services” instead of “purchasing” – includes outsourced processes
- Elimination of specific requirements for
 - Quality Manual
 - Management representative

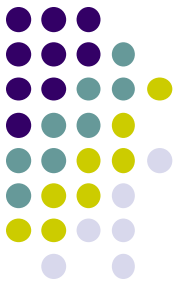
Structure of ISO 9001:2015



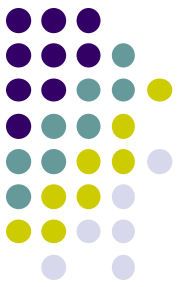
(Slide Courtesy of Alan Daniels; Boeing)



Implementation guidance



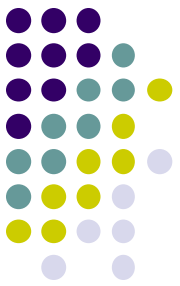
- Work is underway to develop generic implementation guidance for ISO 9001:2015
 - to be numbered as ISO/TS 9002
 - will incorporate previous guidance for small businesses
- Aim is to have this available at the same time ISO 9001:2015 is published



Transition to ISO 9001:2015

- Scheduled publication date September 2015
- ISO/TC176, ISO/CASCO and IAF have approved a ***3-year transition period***
- All organizations are strongly encouraged to start the transition now the DIS is published (mid-2014)
 - Aim is to avoid “peak” of audits to the new standard near end of transition period
 - Avoid overload of CB resources

Conclusions

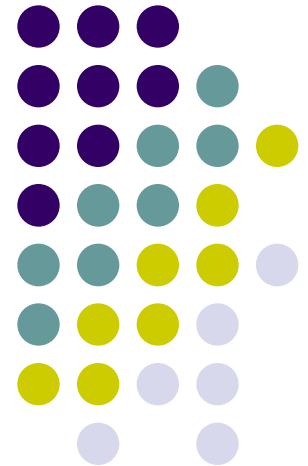


- ISO is aligning its portfolio of management system standards
 - Aim is to facilitate integration
- ISO 9001 is undergoing a “major revision”
 - Now at DIS stage – scheduled publication Sept 2015
 - Significant changes in structure and clause sequence
 - “Process Approach + PDCA + Risk-based thinking”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

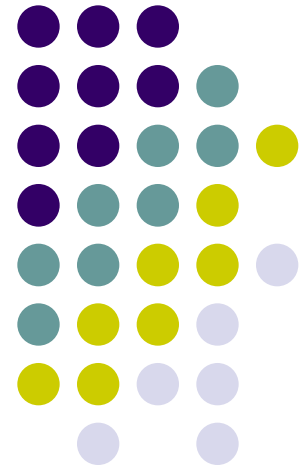
THANK YOU!



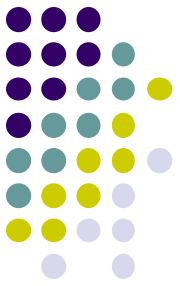
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Some key changes (Based on the Draft International Standard)



4.1 “Understanding the organization and its context”



- Organization shall:
 - determine external and internal issues that are relevant to purpose and strategic direction and that affect ability to achieve the intended result(s) of QMS.
 - monitor and review the information about these external and internal issues.

“Context of the organization”



- External context includes*
 - cultural, social, political, legal, regulatory, financial, technological, economic, natural and competitive environment, whether international, national, regional or local;
 - relationships with, and perceptions/values of external stakeholders
- Internal context includes*
 - corporate culture;
 - governance, organizational structure, roles and accountabilities;
 - policies, objectives, and strategies
 - resources (capital, time, people, processes, systems technologies);
 - information systems, information flows and decision-making processes (both formal and informal)

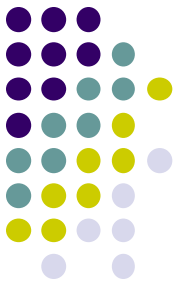
* (taken from ISO 31000)

4.2 “Understanding the needs and expectations of interested parties”



- “The organization shall
 - determine -the interested parties ***that are relevant*** to the QMS,
 - determine -the related requirements of these interested parties ***that are relevant*** to the QMS”
 - monitor and review the information about these interested parties and their relevant requirements
- ISO 9001:2015 focuses attention on those interested parties that can impact the organization’s ability consistently provide conforming products and services

4.3 Determining the scope of the QMS



The organization shall determine the ***boundaries and applicability*** of the QMS to establish its scope.

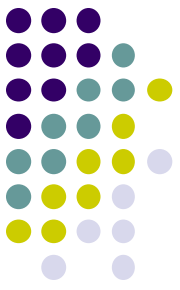
Must consider

- the external and internal issues referred to in 4.1,
- the requirements referred to in 4.2
- products and services provided.

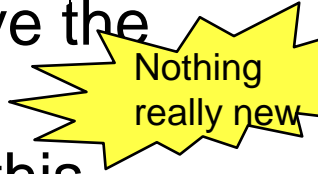
ISO/DIS 9001:2015 includes comments that:

- All requirements are applicable
- If a requirement cannot be applied, it must
 - not affect the ability to provide conforming product
 - be justified

4.4 Quality management system and its processes



“establish, implement, maintain and continually improve the QMS, **including the processes needed and their interactions**, in accordance with the requirements of this International Standard”.

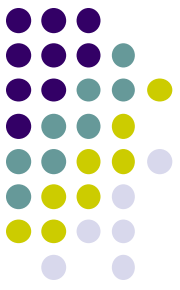


(This is key to maintaining the “process approach”, which will now be embedded in ALL ISO management system standards)





Plus a “Beefed-up” version of current clause 4.1 of ISO 9001:2008 , with new requirements as follows:

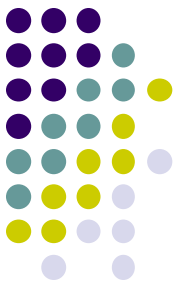


4.4 QMS and its processes (contd)



Organizations shall determine:

- ***inputs required and outputs expected*** from the QMS processes; 
- criteria, methods, ***including measurements and related performance indicators*** needed to ensure the effective operation and control; 
- assignment of the ***responsibilities and authorities*** for these processes; 
- ***risks and opportunities*** and plan and implement appropriate actions to address them; 



5.1 Leadership and commitment

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

NEW Taking accountability of the effectiveness of the QMS;

NEW Ensuring policy and objectives are **compatible with strategic direction**

NEW Ensuring the quality policy is **communicated, understood and applied**

NEW **ensuring integration** of the QMS requirements into business processes

NEW **promoting awareness of the process approach;**

NEW Communicating importance of effective quality management and of conforming to the QMS requirements;

NEW **ensuring that the system achieves its intended results**

NEW **engaging, directing and supporting persons** to contribute to the effectiveness of the QMS;

NEW Promoting continual improvement

NEW **supporting other relevant management roles to demonstrate their leadership** as it applies to their areas of responsibility.”

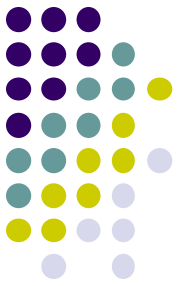
5.1 Leadership and commitment



Top management is also required to ensure that:

- customer requirements and applicable statutory / regulatory requirements are determined and met;
- the ***risks and opportunities*** that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
- ***the focus on consistently providing products and services that meet customer and applicable statutory and regulatory requirements is maintained***;
- the focus on enhancing customer satisfaction is maintained.

5.2 Quality Policy



“Top management shall establish a quality policy that:

- Is appropriate to the purpose of the organization,
- provides a framework for setting quality objectives;
- includes a commitment to satisfy applicable requirements, and
- includes a commitment to continual improvement of the quality management system



The quality policy shall

- be available as documented information
- be communicated within the organization
- ***be available to interested parties, as appropriate.***”



5.3 Organizational roles, responsibilities and authorities



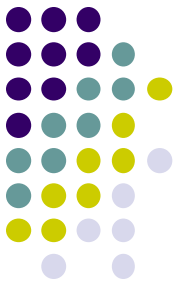
Top management shall assign the responsibility and authority for.....



- ensuring that the processes are delivering their intended outputs;
- reporting on the performance of the quality management system, on opportunities for improvement and on the need for change or innovation, and especially for reporting to top management;

This is typically what we would expect from the “Management Representative”, though this name is no longer used

6.1 Actions to address risks & opportunities



“**determine the risks and opportunities** that need to be addressed to

- give assurance that the QMS can achieve its intended result(s)
- prevent or reduce undesired effects
- achieve continual improvement.

Plan:

a) **actions to address these risks and opportunities**, and

b) how to

- integrate and implement these actions into the QMS processes
- evaluate the effectiveness of these actions.”

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

NOTE Options can include: avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

6.2 Quality objectives and planning to achieve them



“The organization shall establish quality objectives at relevant functions, levels **and processes**.

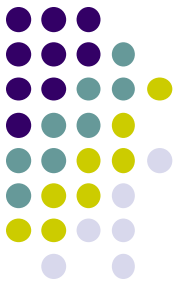


The quality objectives shall

- be consistent with the quality policy
- be **measurable**
- take into account applicable requirements
- be relevant to conformity of products and services and the enhancement of customer satisfaction;
- be **monitored**
- be communicated, and
- be updated as appropriate.



6.2 Quality objectives and planning to achieve them (contd..)




“When planning how to achieve its quality objectives, the organization shall determine

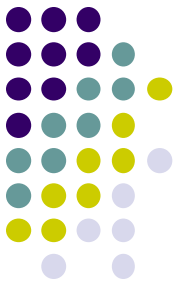
- **what** will be done
- **what resources** will be required
- **who** will be responsible
- **when** it will be completed
- **how** the results will be evaluated.”



6.3 Planning of changes

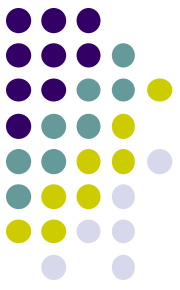
Where there is a need for change to the QMS this must be done in a planned and systematic manner, considering:

- the purpose of the change and any potential consequences; 
- the integrity of the QMS
- the availability of resources;
- allocation or reallocation of responsibilities and authorities.



7 Support Processes

- Resources
- Competence
- Awareness
- Communication
- Documented information



7.1 Resources

- The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the QMS.
- ISO 9001:2015 will include additional requirements:

- People
- Infrastructure
- Process environment
- Monitoring & measuring resources
- Organizational knowledge

Nothing really new

Previously
“Work environment”

Nothing really new

NEW

7.1.6 Organizational Knowledge

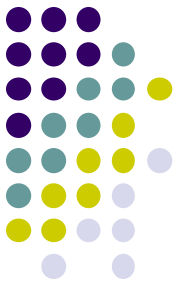


.....When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access the necessary additional knowledge:

- can include information such as intellectual property and lessons learned
- can consider:
 - internal sources (e.g. learning from failures and successful projects, capturing undocumented knowledge and experience of topical experts within the organization);
 - external sources (e.g. standards, academia, conferences, gathering knowledge with customers or providers).

(Remember Deming - “There is no substitute for profound knowledge of the business!”)

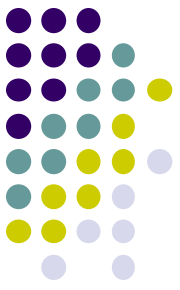
7.2 Competence



“The organization shall

- determine the necessary competence of person(s) ***doing work under its control that affects its quality performance***,
- ensure that these persons are competent on the basis of appropriate education, training, or experience;
- where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken
- retain appropriate documented information as evidence of competence.

NOTE Applicable actions may include, for example: the provision of training to, the ***mentoring*** of, or the ***re-assignment*** of currently employed persons; or the ***hiring or contracting of competent persons***.”



7.3 Awareness

“**Persons doing work under the organization’s control** shall be aware of:

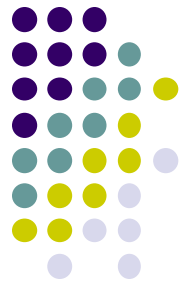
- the quality policy and relevant objectives
- **their contribution to the effectiveness** of the QMS, including the benefits of improved quality performance
- **the implications of not conforming** with the QMS requirements.”

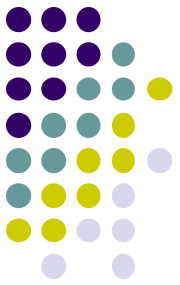


7.4 Communication

“The organization shall determine the *internal and external* communications relevant to the QMS including

- *on what* it will communicate
- *when* to communicate
- *with whom* to communicate
- *how* to communicate”



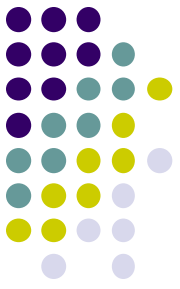


7.5 Documented information



Previously known as “documents and records”

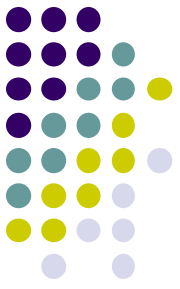
- “Documents” need to be “**main**tained as documented information”
- “Records” need to be “**re**tained as documented information”



8 Operation

- Operational planning and control
- Determination of customer requirements
- Design and development of products and services
- Control of external provision of products and services (Purchasing and outsourcing addressed together)
- Realization and provision of products and services
- Release of products and services
- Control of nonconforming products and services

8.1 Operational planning and control



“**Plan, implement and control the processes needed to meet requirements for the provision of products and services**, and to implement the actions determined in 6.1 by:

- determining requirements for the products and services
- establishing criteria for the processes and **acceptance criteria**
- determining the resources needed
- implementing the control of processes
- retaining documented information”



“Control planned changes and review the consequences of unintended changes, **taking action to mitigate any adverse effects**, as necessary”

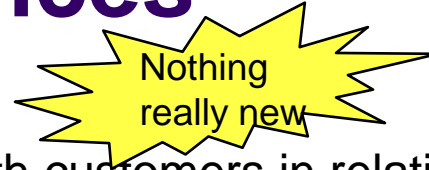


“Ensure that outsourced processes are controlled.”

8.2 Determination of requirements for products and services



8.2.1 Customer communication



Establish the processes for communicating with customers in relation to:

- information relating to products and services;
- enquiries, contracts or order handling, including changes;
- obtaining customer views and perceptions, including customer complaints;
- handling or treatment of customer property, if applicable;
- specific requirements for **contingency actions**, when relevant



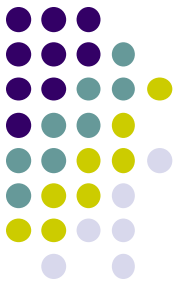
8.2.2 Determination of requirements.

Process to determine the requirements for the products and services to be offered to potential customers.

- **Ensure the organization has the ability to meet the defined requirements and substantiate the claims for the products and services it offers.**



8.3 Design and development of products and services



“Where the detailed requirements of the organization’s products and services are not already established or not defined by the customer or by other interested parties, such that they are adequate for subsequent production or service provision, the organization shall establish, implement and maintain a design and development process.



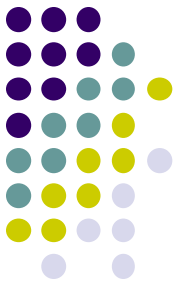
- The organization can also apply the requirements given in 8.5 to the development of processes for production and services provision
- For services, design and development planning can address the whole service delivery process. The organization can therefore choose to consider the requirements of clauses 8.3 and 8.5 together.



(Remainder of design & development clause has been maintained and/or simplified compared to ISO 9001:2008)

8.4 Control of externally provided products and services

Previously
"Purchasing"



Ensure that externally provided **processes**, products, and services conform to specified requirements.

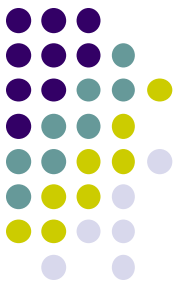
Apply the specified requirements for the control of externally provided products and services when:

- products and services are provided by external providers for incorporation into the organization's own products and services;
- **products and services are provided directly to the customer(s) by external providers on behalf of the organization;**
- a process or part of a process is provided by an external provider as a result of a decision by the organization to outsource a process or function.
- Type and extent of controls to be applied depends on:
 - potential impact of the externally provided processes, products and services
 - perceived effectiveness of controls applied by external provider.

NEW

NEW

8.5 Production and service provision

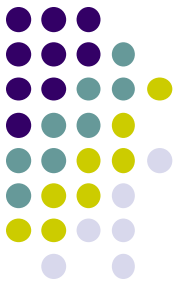



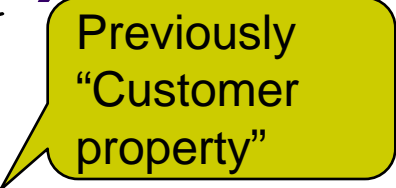
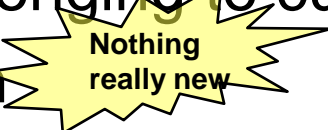


Implement controlled conditions for production and service provision, including delivery and post-delivery activities. This can include:

- definition of the product and service characteristics (documented);
- activities to be performed and results to be achieved (documented);
- monitoring and measurement activities
- use and control of suitable infrastructure and process environment;
- availability and use of suitable monitoring and measuring resources;
- competence and, where applicable, required qualification of persons;
- validation, and periodic revalidation, of “special processes”;
- formal release of products and services, delivery and post-delivery activities.



8.5 Production and service provision (continued)



- Identification and traceability 
- Property belonging to customers **or external providers** 
- Preservation 
- Post-delivery activities – Consider: 
 - **risks associated with the products and services;**
 - **nature, use and intended lifetime**
 - **customer feedback;**
 - **statutory and regulatory requirements.**
- Control of changes 
 - review and control unplanned changes essential for production or service provision to ensure continuing conformity

8 Operation (continued)



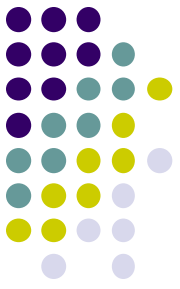
Nothing really new

Previously Clause 8.2.4 of ISO 9001:2008

- 8.6 Release of products and services
- 8.7 Control of nonconforming **process outputs**, products and services
 - Now requires actions taken to be documented
 - includes any concessions obtained
 - **details of person or authority that made the decision regarding dealing with the nonconformity.**

NEW

NEW



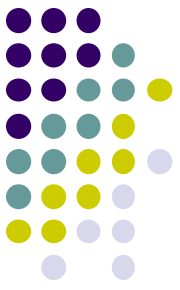
9 Performance evaluation

- Monitoring, measurement, analysis and evaluation
 - General
 - Customer satisfaction
 - Analysis and evaluation of data
- Internal Audit
- Management review

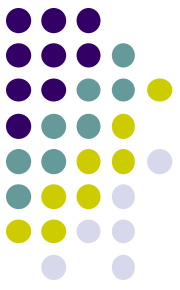
Nothing
really new

Nothing
really new

9.1 Monitoring, measurement, analysis and evaluation





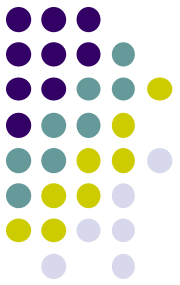
- Determine:
 - **what** needs to be monitored and measured
 - **methods** for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results
 - **when** the monitoring and measuring shall be performed
 - **when** the results from monitoring and measurement shall be analysed and evaluated.
- Retain appropriate documented information.
- Evaluate the quality performance and the effectiveness of the QMS



9.3 Management review

Now includes requirements to consider:

- changes in external and internal issues that are relevant to the QMS and strategic direction; 
- information on the quality performance, ***including trends and indicators*** for: 
 - monitoring and measurement results;
 - issues concerning external providers and other relevant interested parties;
 - adequacy of resources
 - effectiveness of actions taken to address risks and opportunities



10 Improvement

- General
- Nonconformity and corrective action
- Continual improvement

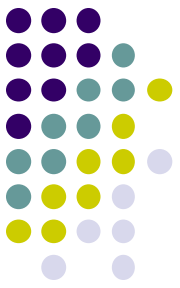
10.1 General



- Implement actions to meet customer requirements and enhance customer satisfaction, by:
 - improving processes to prevent nonconformities;
 - improving products and services to meet known and predicted requirements;
 - improving quality management system results.
- NOTE: “Improvement” includes more than just continual improvement (“Kaizen”)
 - May also include breakthrough improvements, innovation, transformation etc.



10.2 Nonconformity and corrective action



“When a nonconformity occurs, the organization shall:

a) react to the nonconformity, and as applicable

- take action to **control and correct it**, and
- **deal with the consequences**;

b) evaluate the need for action to eliminate the causes of the nonconformity, **in order that it does not recur or occur elsewhere**, by

- reviewing the nonconformity
- **determining the causes** of the nonconformity, and
- determining if similar nonconformities exist, or could potentially occur;

c) implement any action needed;



d) review the effectiveness of any corrective action taken; and

e) make changes to the quality management system, if necessary.”



10.3 Continual improvement



- Consider outputs of analysis and evaluation, and outputs from management review, to ***identify areas of underperformance or opportunities for improvement.*** 
- ***Select and utilise applicable tools and methodologies*** for investigation of the causes of underperformance and for supporting continual improvement. 

Contact us today



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