

# Future trends for ISO 9001 and accredited certification.

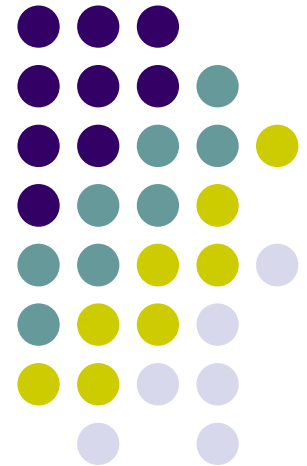
**Nigel H Croft**

**Chairman, ISO/TC176/SC2 – Quality Systems**

**Member, ISO/TC176 Chairman's Strategic Advisory Group**

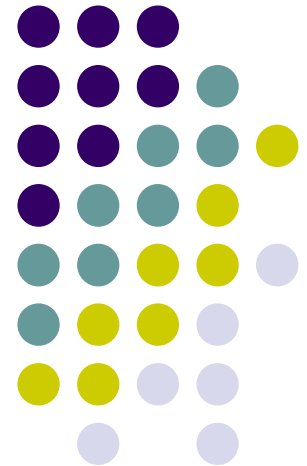
**Member, ISO/CASCO Chairman's Policy Committee**

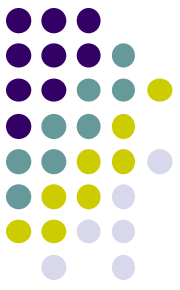
**Member, IAF/ILAC/ISO Joint Working Group**



# Part 1

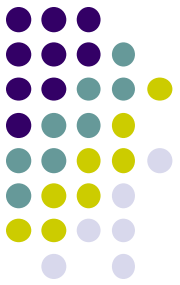
Latest developments in the  
ISO 9000 family, and  
plans for the future of  
ISO/TC176/SC2





# Overall Scenario of TC176

- Development of generic QMS standards that have broad application:
  - all market sectors
  - both private and public organizations
- +/- 1,000,000 worldwide certifications to ISO 9001
- Other guidelines produced by ISO/TC 176 assist organizations in improving their quality management processes.
  - ISO 9000
  - ISO 9004
  - Others (ISO 10001/2/3; ISO 19011 etc)



**ISO/TC 176**

**CALG**

**CSAG**

**Automotive TG**

**Spanish Trans TG**

**Arabic Trans TG**

**SC 1**

**SC 2**

**SC 3**

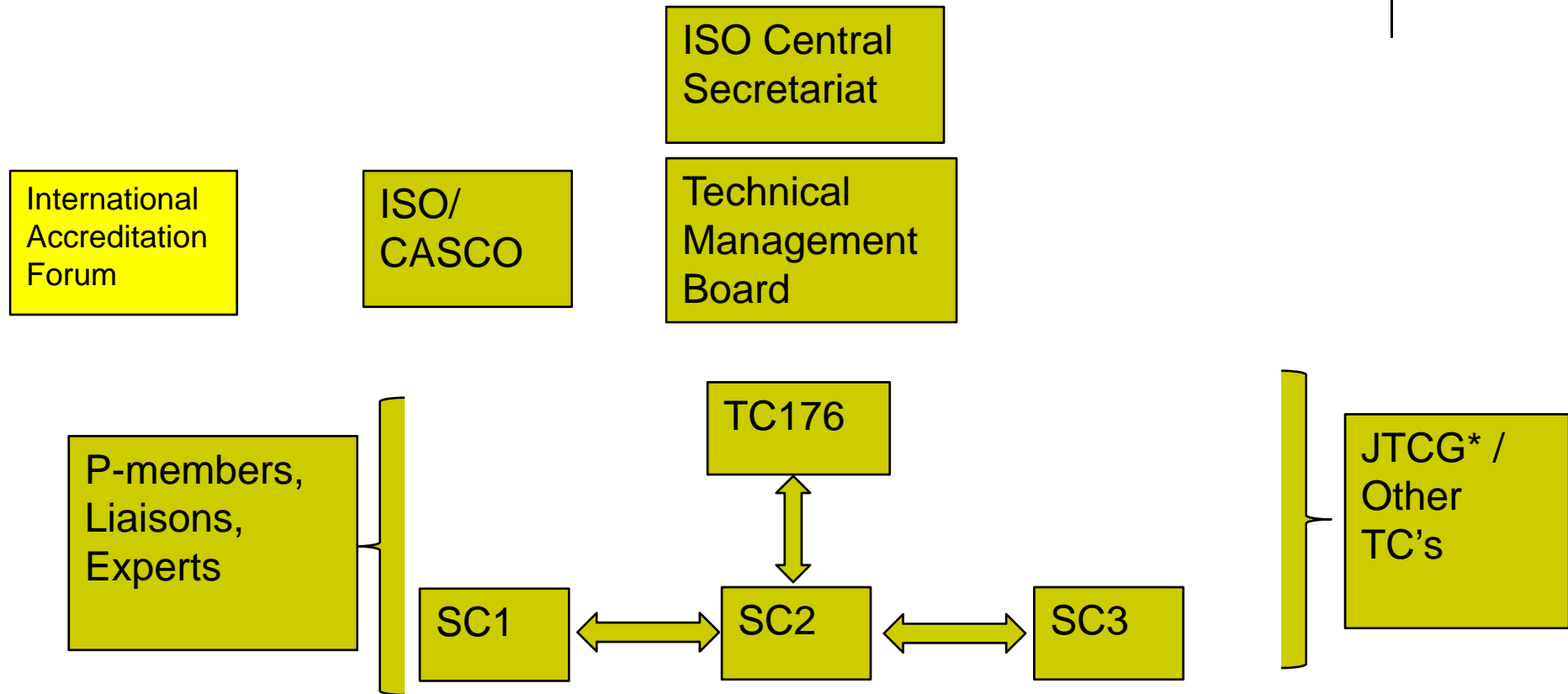
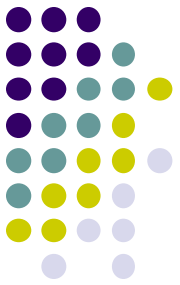
**WG18  
(to be disbanded)**

**WG  
Interp**

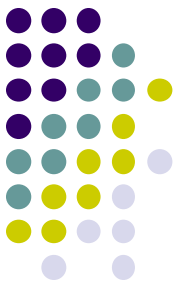
**TG "Future  
Concepts for ISO  
9001"**

**ISO 9001  
ISO 9004  
& others**

# SC2 Organizational Environment....



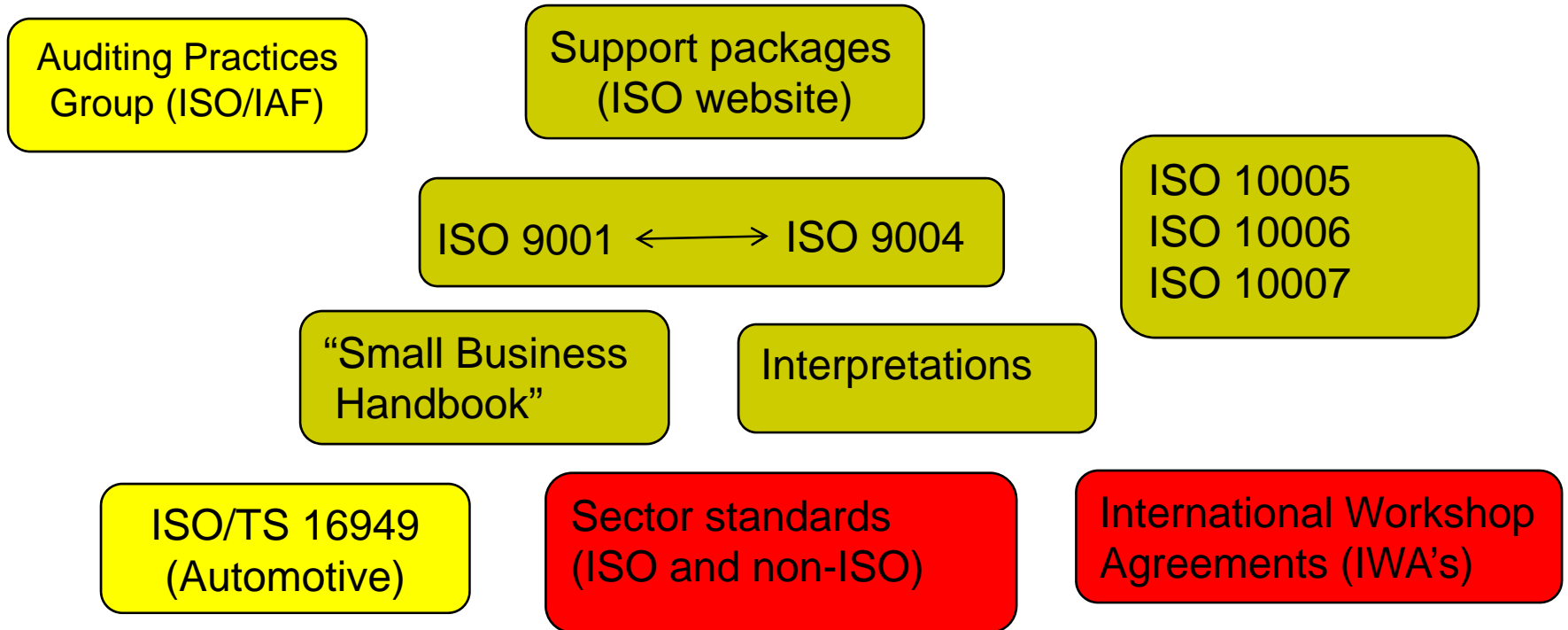
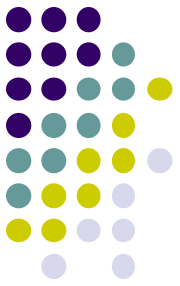
\* Joint Technical Coordination Group



# Relationships with TC176.....

- Participate actively in strategy development via CSAG
  - TC176 Strategic Plan
  - TC176 “Portfolio”
- Commit to deploy TC176 policies and strategies via active participation in TCOG
  - Liaison with other SC’s within TC176
  - Liaison with other organizations outside of TC176
    - JTCCG; CASCO; IAF; Sectors etc

# Current SC2 Portfolio and “Ecosystem”

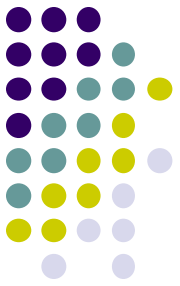




# ISO 9001:2008

- Primary objectives were:
  - to improve the existing ISO 9001:2000 standard;
  - to provide greater clarity and ease of use,
  - to improve compatibility with ISO 14001:2004
- All changes submitted to “benefit versus impact” analysis
- Main changes
  - “No new requirements” (at the “macro-level”)
  - Changes to the wording of some clauses (“Micro-level”)
    - Better understanding of requirements could lead to a need for change.
    - The changes are small, but provide opportunities for organizations to take a step back & look at the overall effectiveness of their QMS

# Implications of ISO 9001:2008



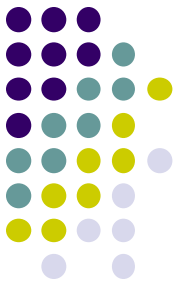
- Changes were very small (but not “trivial”)
- Some changes could not be incorporated due to potentially large impact
  - TC176/SC2 formed Task Group to look at “Future Concepts for possible incorporation into ISO 9001”
- Long-term Strategic Planning for ISO/TC176 and TC176/SC2 underway, looking at entire portfolio and “architecture”

# Some of the topics being discussed as “Future Concepts for ISO 9001”....



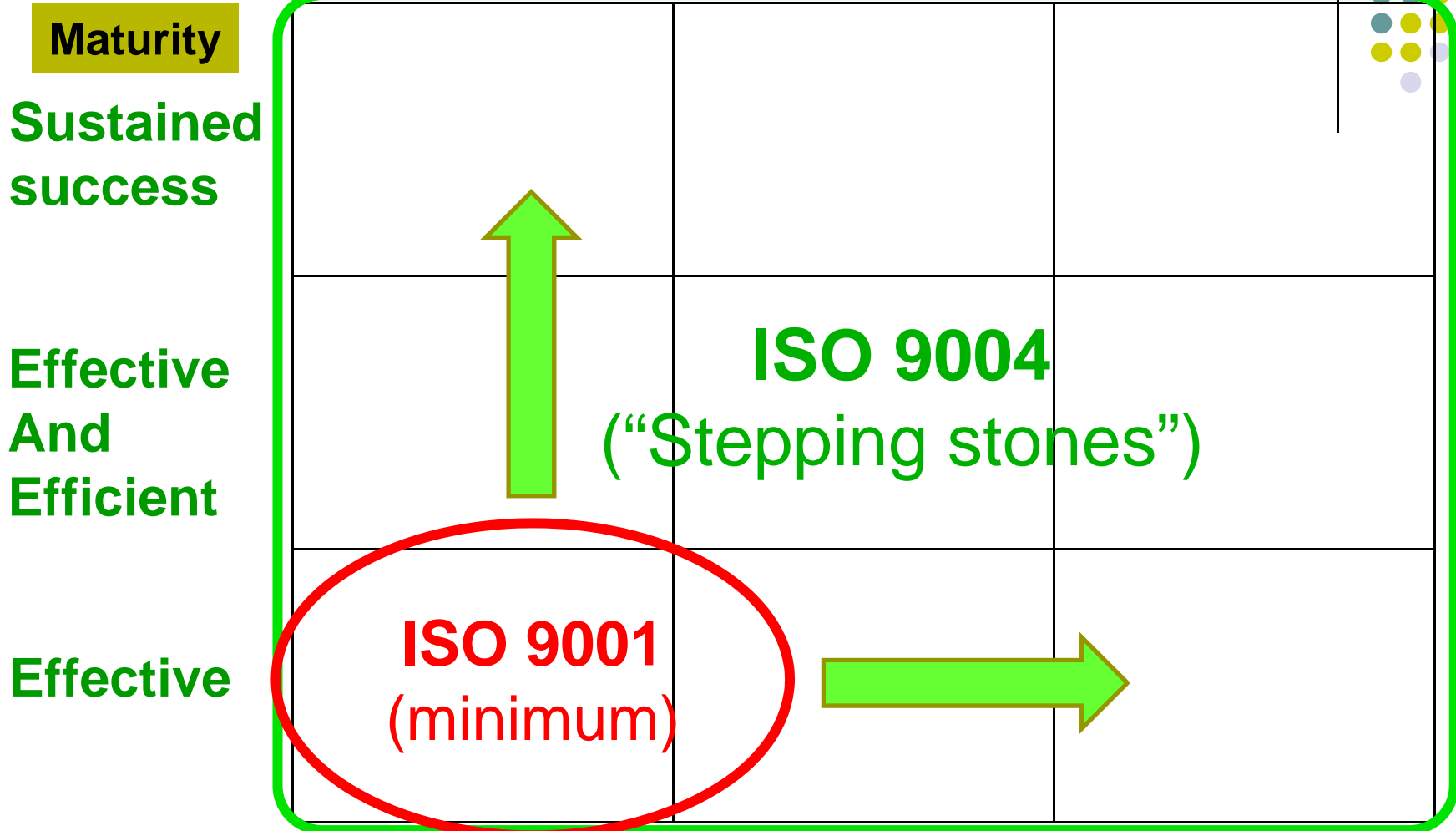
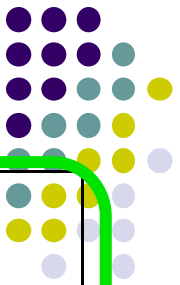
- Integration of risk management
- “Output matters”
- Knowledge management
- Life cycle management (LCM)
- Improvement and innovation
- “Time/Speed/Agility”
- Technology and Changes in IT

# ISO 9004:2009



- Very different from ISO 9004:2000, both in structure and content.
- Basis is still the eight quality principles but with additional ideas incorporated:
  - Vision/mission/strategy development, innovation and learning.
- ‘Guidelines for self-assessment’ have evolved into a ‘Self-assessment tool’ (Annex A).
  - Guidance on two levels: one for top management and the other at an operational level.
- Risks are treated in a more visible way than before.
- No more direct ISO 9001 quotations (“ISO 9001 boxes”) in the text.

# Relation between ISO 9001 and ISO 9004



**Customers** → **"All interested parties"**

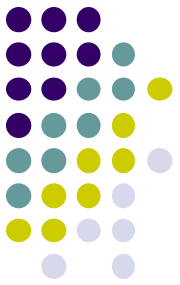
**"Realization processes"** → **"All processes"**

# Messages I'm hearing about ISO 9001.....

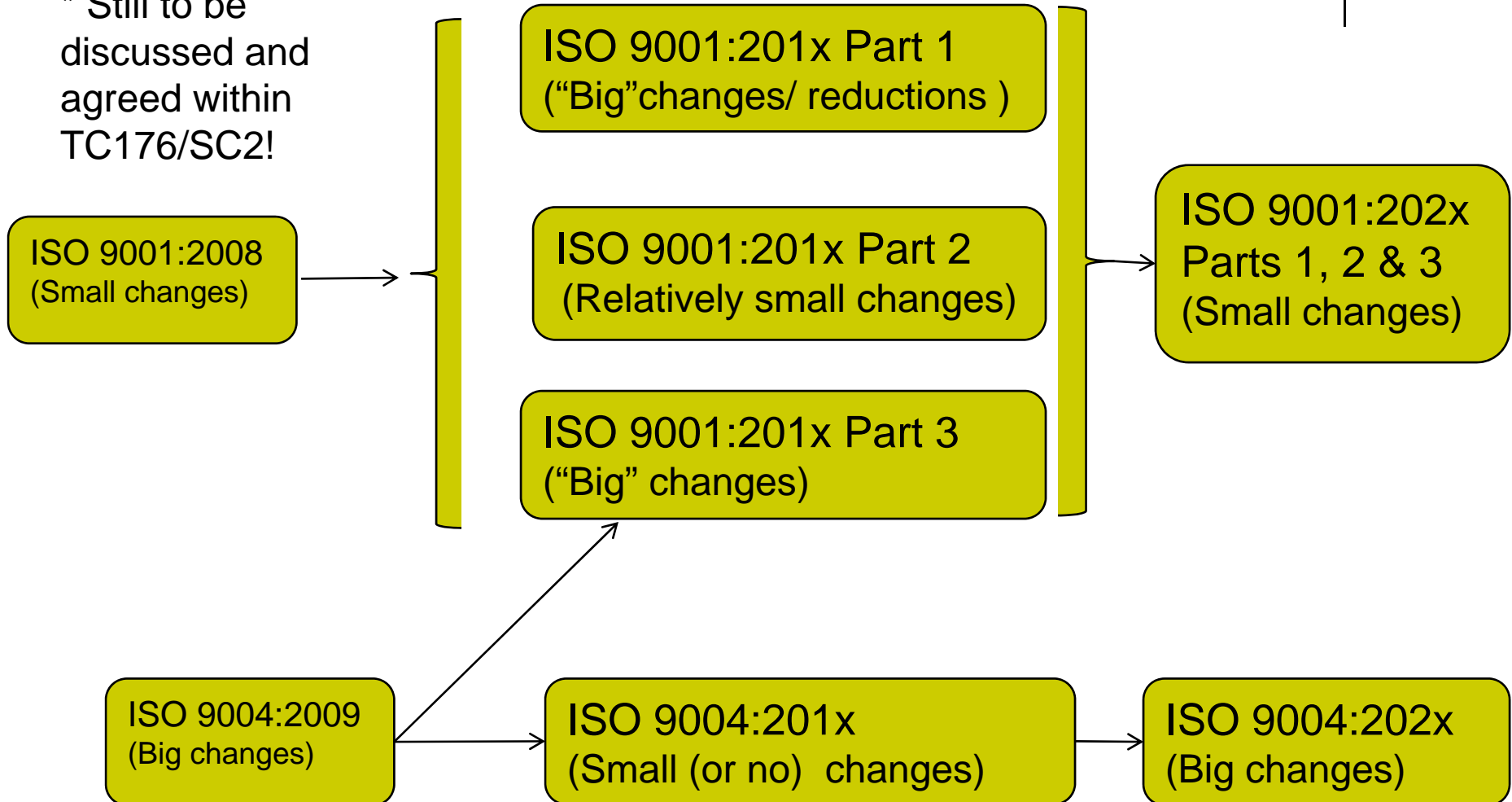


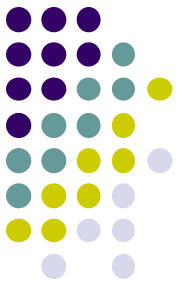
- From many users.....
    - “We want NO CHANGE”
  - From High-tech (high risk) and/or mature users.....
    - “We want MORE!” (“We want to show we’re “BETTER!”)
  - From Low-tech (Low risk) and/or immature users and SME’s\*
    - “We want LESS!” (“We want an easier option”)
- \* NOTE – I don’t agree that this is a function of SIZE
- From the “Future Concepts for ISO 9001” TG
    - “Risk Management” ; “Output matters” etc
  - From the TC Chair
    - “CMM”! (Capability Maturity Model)
  - From some sectors
    - “User-friendly GUIDANCE”

# One option for the future direction of ISO 9001 and ISO 9004 \* .....



\* Still to be discussed and agreed within TC176/SC2!





# ISO 9001:201x

- Part 1

- Would be aimed at low-risk / low criticality organizations
- Many SME's will come into this category (but not necessarily!)

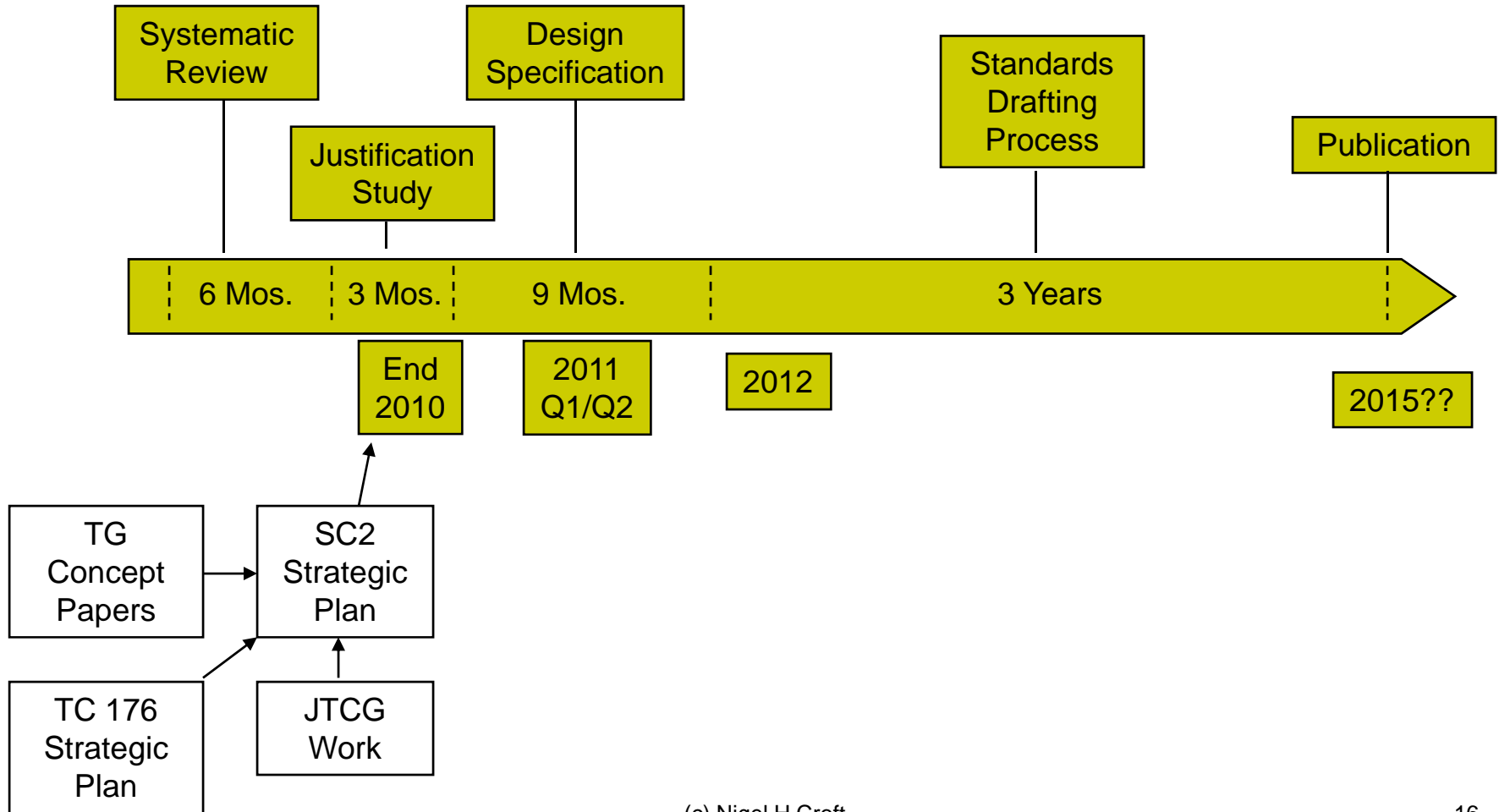
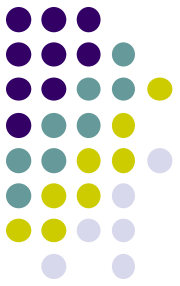
- Part 2

- “Default” – would be a continuation of ISO 9001:2008 with relatively small changes
- Basis for regulatory requirements, sector schemes etc

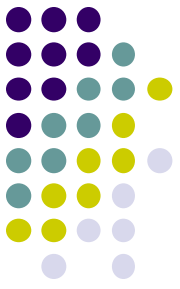
- Part 3

- Would be aimed at high-risk / high criticality organizations
- Plus mature organizations seeking a “differential”

# High-Level Timing for ISO 9001



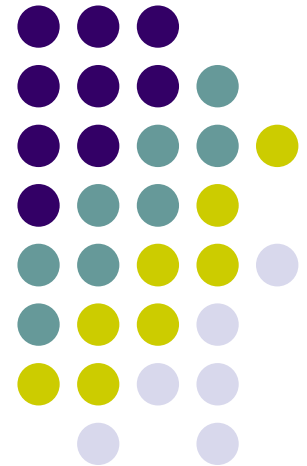
# Other things happening in TC176.....



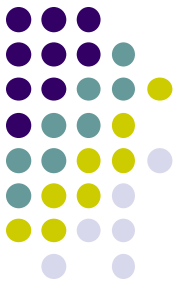
- Guidance documents for ISO 9004:2009 out for comment – to be published mid-2010 on ISO website
- ISO 9001 Small Business Handbook recently updated
- ISO 19011 being revised (includes other management systems)
- In preparation by SC3:
  - ISO/TS 10004 Guidelines for monitoring and measuring Customer Satisfaction)
  - ISO/TS 10008 E-commerce transactions
  - ISO/TS 10018 “People aspects of quality”

# Part 2

The future of accredited  
certification to ISO 9001

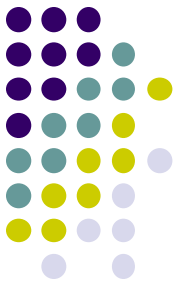


# The challenges.....



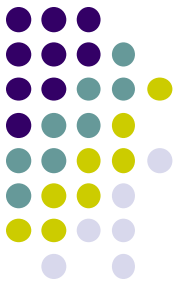
- ***Downward spiral for QMS confidence (Japanese study)***
  - Focus on certification, not quality
  - Certification becomes a commodity
  - Pressure from direct customers
  - Prices (auditor days and day-rates) driven down
  - Difficulty to recruit competent auditors
  - More “superficial” audits
  - Loss in confidence of CB’s “clients’ customers”
- ***“The ultimate accreditation is from the clients’ customers”***
  - Risk of taking matters into their own hands
    - Auto industry (IATF)
    - Large purchasers returning to 2<sup>nd</sup> party audits
    - Possibility of government regulation

# Joint ISO/IAF Action Plan



- Developed by IAF/ILAC/ISO Joint Working Group
- Key elements
  - Recognition that **“OUTPUT MATTERS”**
    - Is the management system delivering on its promise?
  - Need for CB’s to focus on “the clients’ customers”
    - Are they satisfied with their supplier’s **performance**?
  - Need for a **more aggressive posture** from ALL “PLAYERS” in the conformity assessment community
    - To separate the “Good Guys” from the “Bad Guys”

# Some key developments.....



- ISO/IEC 17021 published in 2006
  - Requirements for CB's
  - Principles-based approach
  - Systematic approach to managing conflicts of interest
  - Two-stage initial audit required
- ISO/IEC 17021 Part 2 to be published in 2010
  - More focus on audit process and auditor competence

# Some key developments (Cont.....)



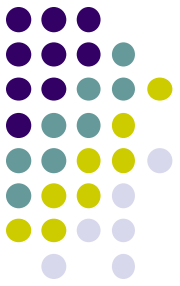
- Joint ISO/IAF Communiqué (June 2009) *“Expected Outcomes from Accredited Certification to ISO 9001”*
- Update of ISO 9000 Advisory Group Document *“ISO 9001 – What does it mean in the supply chain?”*
- Joint ISO/IAF Guidance on *“Good Auditing Practice”*
  - Aimed at 3<sup>rd</sup> party auditors, but also useful for internal auditors!
  - Similar set of guidance for Accreditation Body Assessors
- All are available for **free download** from [www.iso.org](http://www.iso.org) and/or [www.iaf.nu](http://www.iaf.nu)

# Some key developments (Cont.....)



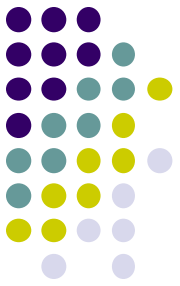
- IAF Mandatory Documents published, including:
  - Audit duration
  - Multiple (and temporary) sites
  - Transfer of certification
- IAF Guidance Documents published, including:
  - “Cross-frontier accreditation” – aimed at better collaboration between AB’s
- New IAF End-user committee established (2008)

# Some key developments (Cont.....)

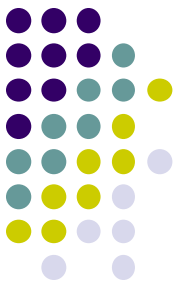


- IAF Task Groups working on following topics:
  - “Harmonization of Sanctions”
  - “Accreditation Market surveillance of certified organizations”
  - Use of CB performance indicators (“Metrics”)
  - End-user feedback
  - Competence criteria for AB Assessors
  - Management of certification during crises (Natural disasters; pandemics; etc)
  - Criteria for accreditation transfer

# Some key developments (Cont.....)



- Joint UNIDO/ISO/IAF project *“Impact of ISO 9001 certification in Asian developing economies”*
  - Objective is to verify
    - Knowledge and satisfaction level of purchasers
    - Performance of QMS in certified organizations
    - Effectiveness of certification process
  - Methodology includes:
    - Survey of major institutional purchasers (2009)
    - Survey of certified organizations (2010)
    - Visit to over 700 (!) certified organizations (2010)
- Possible extension to other regions (2011)
- Possible incorporation into IAF routine (“market surveillance”)



# Conclusions

- ISO/TC176/SC2 is committed to ensuring the ongoing relevance and credibility of our key standards.
- Strategic planning process for the next 10 years is underway. Expected to be completed by Dec 2010
- We will work as an integral part of ISO/TC176, and with other TC's (via JTCCG) to ensure maximum user-friendliness.
- There continue to be concerns about credibility of ISO 9001 certification

## ***BUT***

- There's a lot happening to address the problem.....
  - IAG initiatives (Supply chain; Audit Practices etc)
  - ISO/TC176 (Interpretations / update of ISO 9001)
  - ISO/CASCO (ISO 17021 Parts 1 & 2)
  - IAF Strategic Plan ("Output matters!")

# THANK YOU!

Questions?



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