Recent trends in management system certification

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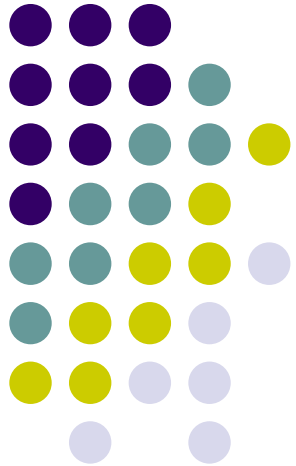
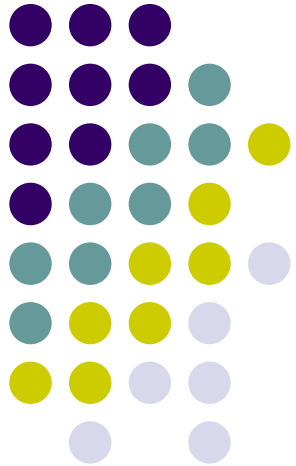
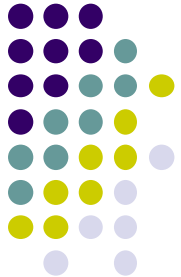


Changes introduced in ISO 9001:2008

"Small changes, Big Opportunities"

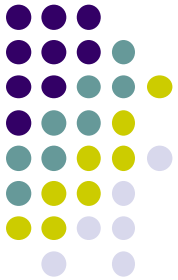


Rationale for new updates……



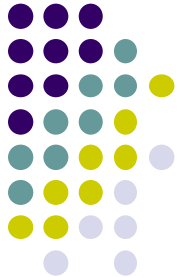
- ISO Review process:
  - Requires continual review (every 5 years) to keep standards up to date.
- User inputs:
  - User questionnaire
  - Suggestions arising from the interpretation process.
  - Opportunities for increased compatibility with ISO 14001
- Current trends:
  - Keeping up with recent developments in management system practices.

Key inputs for ISO 9001:2008



- Web based User Feedback Survey conducted by ISO/TC 176/SC2
- ISO/TC 176 approved interpretations
  - See www.tc176.org/ for details
  - Some interpretation requests indicate need for clarification of ISO 9001 text
- The ISO 9001:2008 Introduction & Support Package set of documents
- ISO 14001:2004

Impacts and benefits



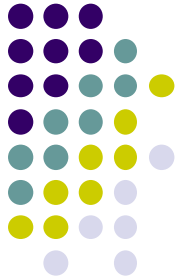
- Changes to ISO 9001 focus on high benefit / low impact cases
- Some high benefit / high impact improvements that were identified are being saved for the next revision cycle
- Criteria are shown in the following slides

Impact analysis

Impact		Benefits		
		1	2	3
		High	Medium	Low
1	Low	1	2	3
2	Medium	2	4	6
3	High	* 3	6	9

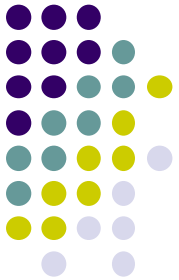
1-2	Incorporate the change.
3-4	Additional analysis should be conducted prior to making the decision.
6-9	Do not incorporate the change. *Note: '*3 - high impact x high benefits' - No change allowed, but we need to record details of proposed change, to provide input into future revisions .*

Main changes in ISO 9001:2008



- “No new requirements” (at the “macro-level”)
- Changes to the wording of some clauses (“Micro-level”)
  - Organizations need to revisit their QMS to check if better understanding leads to a need for change.
  - The changes are small, but they provide BIG OPPORTUNITIES for organizations to take a step back & look at the overall effectiveness of their QMS

Three approaches……..

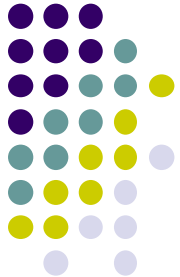


- WRONG!
  - “No new requirements, so I don’t need to do anything”
- “MINIMALIST”
  - “I’ll look through the changes and check if I need to modify my QMS to stay in compliance”
- “PROACTIVE”
  - “Here’s a BIG OPPORTUNITY for me to take a critical look at my system and make improvements”

Some examples……..

- Taken from “ISO 9001:2008 – Small Changes, Big Opportunities” – e-book available (in English) from www.sustainablesuccessalert.com
- Soon to be published in Portuguese (hard copy version)

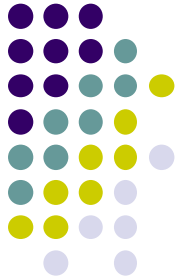
SMALL CHANGE, BIG OPPORTUNITY #1 (Clause 0.1)



Clause 0.1 confirms that the intent of the standard is not to impose uniformity of documentation

- Consider your documentation:
  - Are you in the driving seat, or are you a slave to your documentation?
  - Did it make sense to structure your quality documentation in the way that you have?
  - Does it really help you to manage your processes more effectively?
  - Do the people in your organization understand it?
  - Is it user-friendly?
  - Is it consistent with other documentation in your company?
  - Is there any value to making a change now?
- Why not take this opportunity to streamline your documentation, and eliminate those documents that are not adding value?

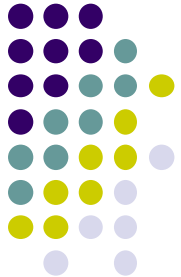
SMALL CHANGE, BIG OPPORTUNITY #2 (Clause 0.1)



Clause 0.1 now refers to the organizational environment, changes in that environment and associated risks.

- **BIG OPPORTUNITY** - check to ensure that your QMS continues to be relevant to the changing business environment in which you are operating.
  - As you grow, your situation may change — new technologies, market opportunities, consumer demands, threats etc.
  - Is the level of detail of your QMS and associated processes still appropriate to the risks involved in your activities?
  - In the current financial climate, you should be looking to your QMS to guide you through troubled times
  - Ensure that despite cutbacks etc, your product or service quality (and with them your reputation) does not suffer.

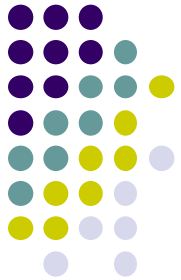
SMALL CHANGE, BIG OPPORTUNITY #4 (Clause 0.2)



Text added to clause 0.2 to emphasize the importance of processes being capable of achieving desired outcomes.

- Probably one of the most subtle but important changes introduced in the new standard.
  - Emphasizes that the QMS should be achieving its primary objective - “consistent, conforming products”
  - Did we all forget this??
    - Too much focus on documents and records, rather than on managing processes to achieve desired results.
    - Take a long, hard look – is your system really producing the desired outcomes for you, your customers, and your employees? If not, then why not? What needs to be changed?

SMALL CHANGE, BIG OPPORTUNITY #15 (Clause 4.1)



Note 1 to Clause 4.1 clarifies that the processes needed for the QMS include not only processes for management activities, provision of resources and product realization, but also those needed for measurement, analysis and improvement.

- The BIG OPPORTUNITY is for you to check and make sure you are managing your measurement, analysis and improvement processes in terms of this clause 4.1.
  - Have you identified the intended outputs?
  - Have you allocated adequate resources?
  - Are you monitoring these processes to ensure they are effective?

SMALL CHANGE, BIG OPPORTUNITY #16 (Clause 4.1)

Clause 4.1 (e) now clarifies that process measurement may not be applicable in all cases (though all processes must be monitored).

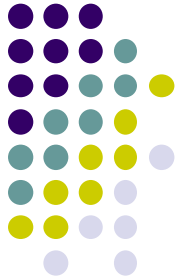
- Do you know the difference between monitoring and measuring?
  - In some cases, you may have been induced by consultants and/or auditors to come up with process measurements that are not practical, meaningful or useful, simply because ISO 9001 was understood to require them.
- Your BIG OPPORTUNITY through ISO 9001:2008 is to re-evaluate the need for such measurements, and to ensure that any measurements that ***are*** necessary really do add value to your organization

SMALL CHANGE, BIG OPPORTUNITY #17 (Clause 4.1)

Notes have been added to explain more about outsourcing – what is meant by an "outsourced process" and what controls might be appropriate

- The BIG OPPORTUNITY is for you to review the way you manage your outsourced processes.
  - Are they being carried out in line with the requirements of ISO 9001:2008?
  - Can you introduce greater efficiencies by considering alternate sourcing or imposing more meaningful monitoring initiatives?
  - Are there any indications of customer dissatisfaction with these processes?
  - Could you benefit from outsourcing other processes?
  - Might it be appropriate to bring some outsourced processes back in-house?

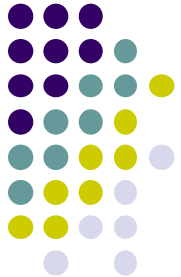
SMALL CHANGE, BIG OPPORTUNITY #21 (Clause 4.2.4)



The sequence of this clause has been changed for greater clarity and better alignment with ISO 14001.

- No real implications, but the BIG OPPORTUNITY would be for you to look at how you might achieve better integration of the records generated by your quality, environmental and other management systems in order to achieve greater efficiency.

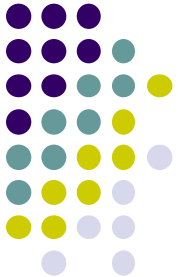
SMALL CHANGE, BIG OPPORTUNITY #23 (Clause 6.2)



ISO 9001:2008 makes an important clarification that competence requirements relate not only to personnel whose work directly affects product quality, but also where it indirectly affects product quality via the operation of the QMS (e.g. purchasing, supplier evaluations, internal audits etc).

- If you have previously limited your attention to competence requirements for personnel directly involved in production or service delivery processes, the BIG OPPORTUNITY is to assess where you may need to include other activities such as those mentioned above, among others.
- This might mean an extra work-load in the short-term, but it is likely to bring long-term benefits.

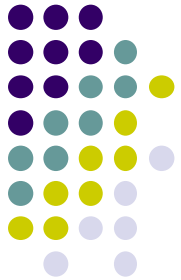
SMALL CHANGE, BIG OPPORTUNITY #25 (Clause 6.3)



This clause now recognizes the importance of information technology (IT) in modern organizations and the effect that information systems can have on product conformity.

- Not a new requirement, but the specific inclusion of IT as an example of infrastructure provides you with a BIG OPPORTUNITY to review your dependence on IT
  - Risk analysis of potential problems should a failure occur (system crash, computer virus, loss of confidential data, file corruption etc).
- No requirement to use IT in your QMS (many organizations can operate quite effectively without it), but where it is used, the risks must be understood and mitigation measures put in place as appropriate.

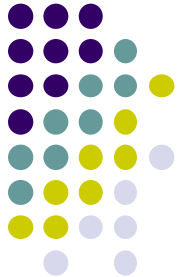
SMALL CHANGE, BIG OPPORTUNITY #32 (Clause 7.5.4)



The note to this clause now explains that both intellectual property and personal data should be considered customer property

- There is a BIG OPPORTUNITY here, particularly if you are working in the service sector.
  - Your customers are no doubt worried about fraud and identity theft, so if you can demonstrate that you are controlling this in an effective way, that should give you a competitive advantage.
  - Such data might include credit card information (internet purchases), address or passport details (hotel check-in) or confidential medical information (health service).

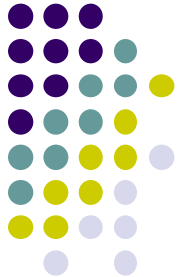
SMALL CHANGE, BIG OPPORTUNITY #35 (Clause 8.2.2)



This clause now expects management responsible for the area being audited to ensure that both correction and corrective actions are addressed as appropriate with respect to detected nonconformities.

- The BIG OPPORTUNITY is that you can now consider the need for correction of detected nonconformities and recognize that it might not be necessary or appropriate to take corrective action for all nonconformities found during internal audits.
  - After a root cause analysis of the situation — and based on a number of factors, including the risk and probability of a recurrence — you might decide that it's sufficient simply to correct the problem, without the need for corrective action.

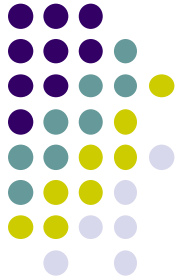
SMALL CHANGE, BIG OPPORTUNITY #36 (Clause 8.2.3)



A note has been added here to clarify that when deciding on appropriate monitoring and/or measurement methods, you should consider both the impact on product conformity and on the effectiveness of your quality management system.

- When QMS processes do not achieve planned results, you must now evaluate the need to make corrections and/or take corrective action, regardless of the direct impact on product conformity.
- BIG OPPORTUNITY is for you to emphasize to all in your organization that it is not only product realization processes that are important.
  - If system processes such as document control, management review, internal audits and others are not achieving planned results, corrections and/or corrective actions will also be needed.

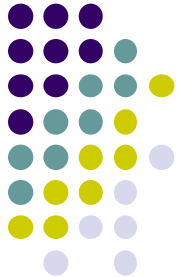
SMALL CHANGE, BIG OPPORTUNITY #37 (Clause 8.5.2)



The standard now makes it clear that it is the effectiveness of the corrective action that must be reviewed, not just the corrective action itself.

- This provides a BIG OPPORTUNITY for you to look carefully at the corrective actions you have initiated, and to make sure they are achieving the intended results.
- If the corrective actions are to address specific nonconformities (in product, process or the quality management system), have they successfully eliminated (or significantly reduced) the problem?

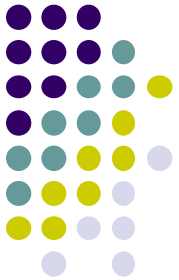
SMALL CHANGE, BIG OPPORTUNITY #38 (Clause 8.5.3)



The standard now makes it clear that it is the effectiveness of the preventive action that must be reviewed, not just the preventive action itself.

- This provides you with a BIG OPPORTUNITY to look carefully at the preventive actions you have initiated, and to make sure they are achieving the intended results.
- If the preventive actions are to address unfavourable trends or specific potential nonconformities (in product, process or the QMS), have they successfully prevented the nonconformity from occurring? Were they successful in terms of cost/benefit?

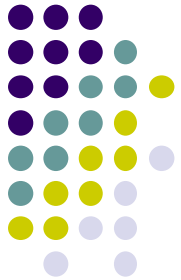
ISO 9001:2008 Implementation Policy



(Joint communiqué published by ISO and IAF)

- November 15th 2008 – Publication of ISO 9001:2008
  - Before publication of ISO 9001:2008 – no accredited certificates to new standard were allowed
- New certificates only after a routine surveillance or recertification audit against ISO 9001:2008.

ISO 9001:2008 Implementation Policy (continued)



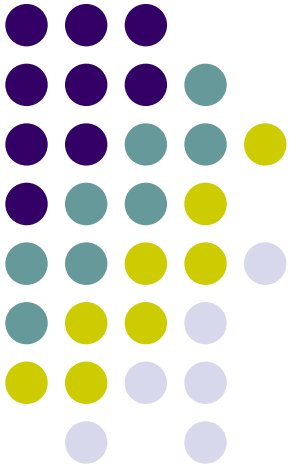
- Up to Nov 15th 2009 – certification / renewal to ISO 9001:2000 still permitted
- Beginning Nov 15th 2009, no new certificates to ISO 9001:2000 allowed – all audits to be conducted to ISO 9001:2008
- From Nov 15th 2010 – ISO 9001:2000 certificates will no longer be valid

Summary

- “Transition” to ISO 9001:2008 should be very simple, but not “automatic”
  - No additional audits should be required
- Auditors need to be aware of changes
  - Use ISO 9001:2008 Annex B
- Organizations should take advantage of the changes to re-assess the value of their QMS and make the most of this BIG OPPORTUNITY
  - Is the QMS really delivering on its promise of “consistent, conforming products”??

ISO/IAF initiatives

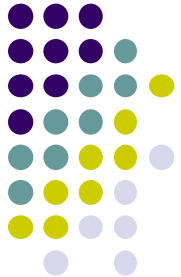
Improving the credibility of ISO 9001 certification



ISO 9001

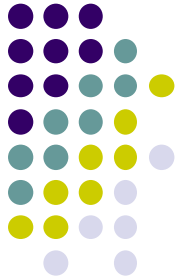
- ***"Developed with tender loving care by ISO's Technical Committee TC176"***
- TC176 Strategic Plan "VISION 2010"
  - Ensure market relevance of TC176 products,
  - Enhance compatibility of management system standards,
  - ***Actively manage liaison relationships, in particular to ensure the continued credibility of ISO/TC 176 products in their use for conformity assessment***

ISO 9001:2008 Scope



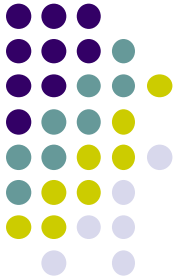
- Clause 1.1 - “Specifies quality management system requirements for organization to:
  - ***demonstrate ability to consistently provide product that meets customer and applicable statutory & regulatory requirements***
  - enhance customer satisfaction……”

WHAT IS CERTIFICATION ALL ABOUT?



- CONFIDENCE
  - Demonstrating that the organization does have a management system conforming to the relevant standard
  - Providing CONFIDENCE to the organization's customers and other stakeholders that the system is effective in achieving the desired outputs
    - ***"Consistent conforming products" (ISO 9001)***
    - ***"Prevention of pollution; regulatory compliance; continual improvement" (ISO 14001)***
    - ***etc***

Who is “The Customer”?

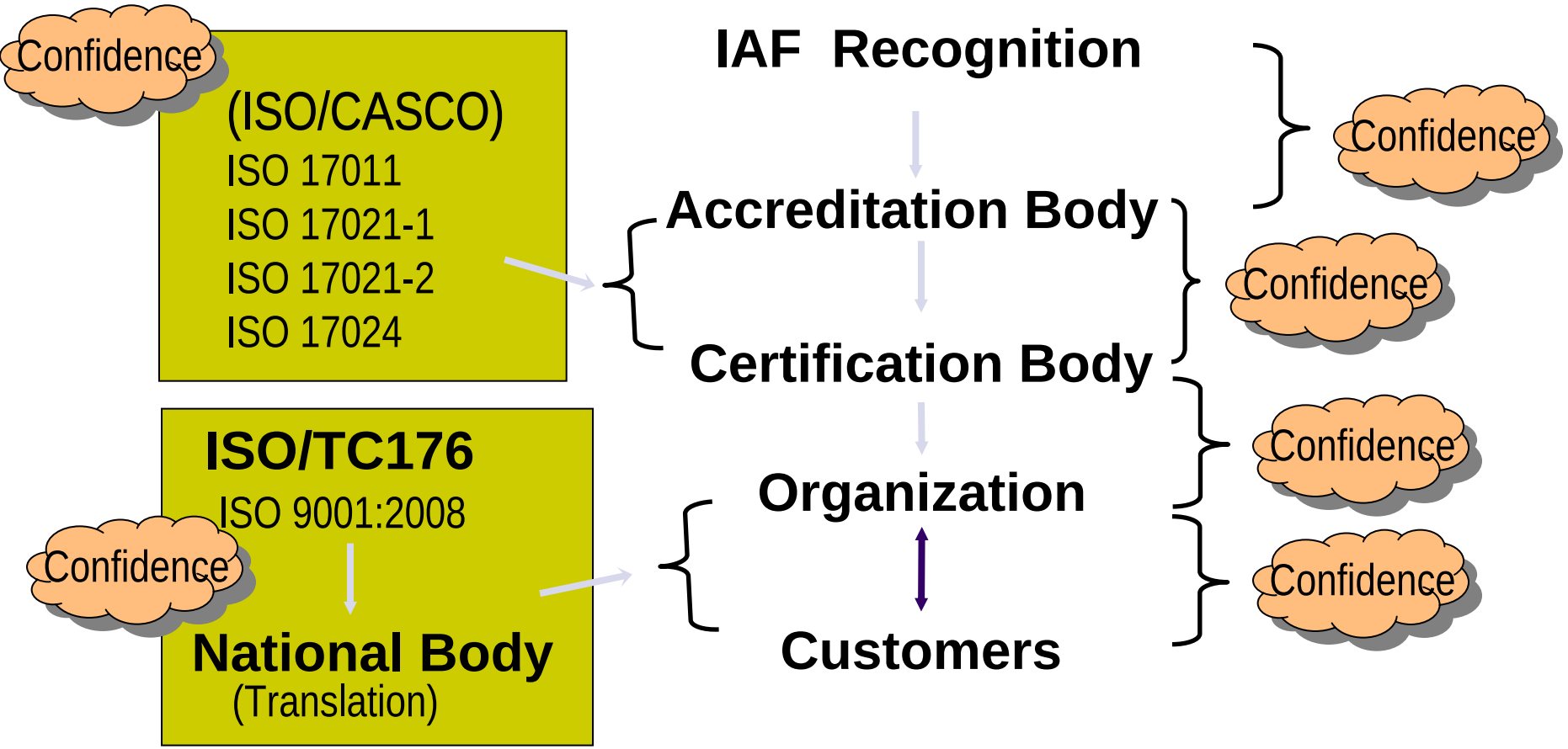


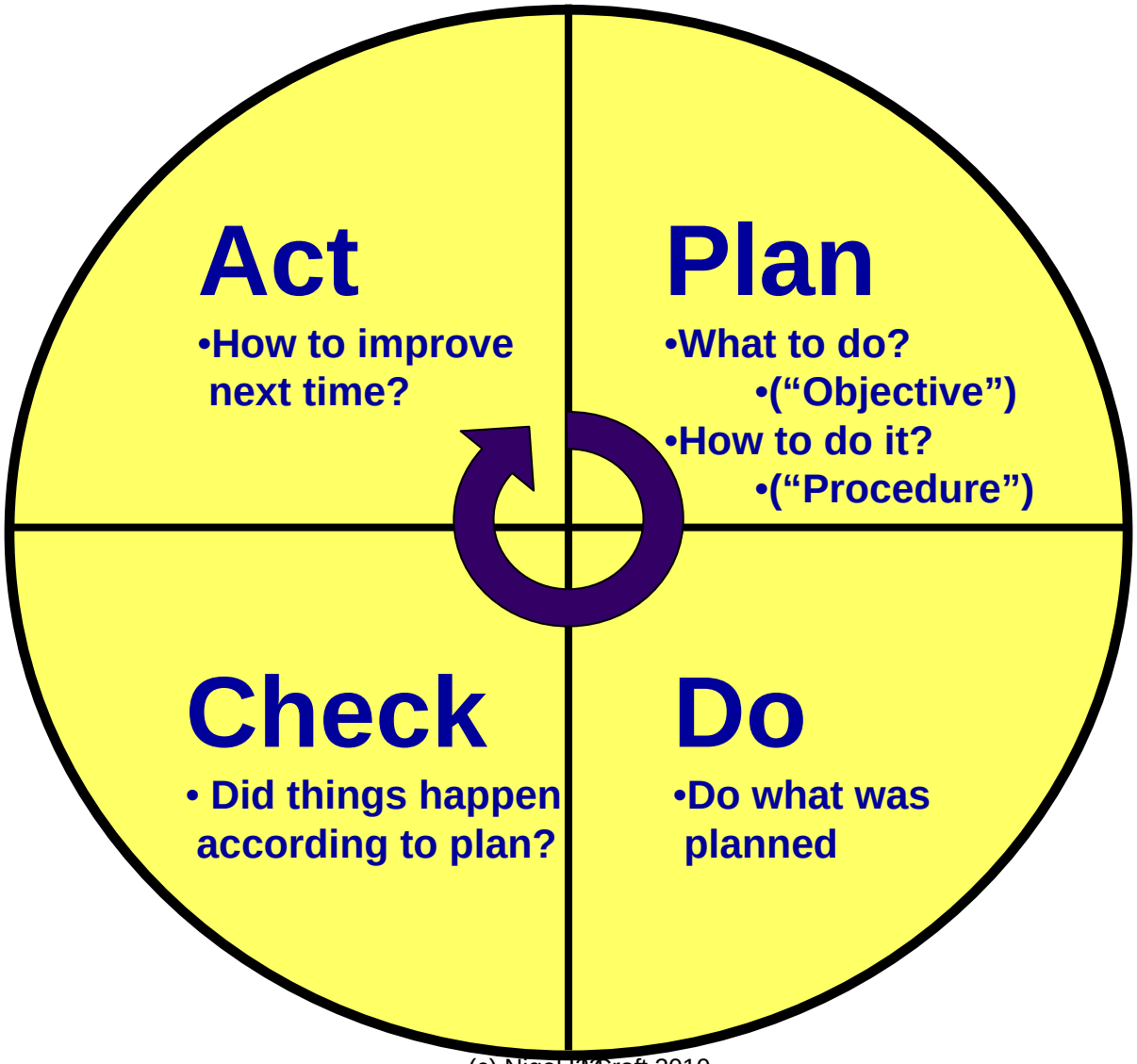
- ISO 9000:2000 definition:
  - “organization or person that receives a product”

- Who is the customer of the certification body?
  - Contractual customer = certified organization
  - ***Ultimate customer = those who purchase or receive products from the certified organization***
    - ***Trust in the ability of a certified organization to consistently provide them with conforming products***

HOW TO PROVIDE CONFIDENCE?

"Chain" of confidence-promoting activities




Act
•How to improve next time?
Plan
•What to do?
•("Objective")
•How to do it?
•("Procedure")
Check
• Did things happen according to plan?
Do
•Do what was planned

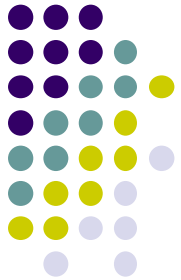
Ongoing confidence (The “C” in the “PDCA” cycle)

- Focus on results
  - Did the ***product*** meet customer requirements? (Customers rarely see the quality management system!)
  - If **YES**, Confidence in certification INCREASES
  - If **NO**, customers lose confidence in certification, and “ISO 9000” credibility suffers

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 2nd party audits
    - Possibility of government regulation

Joint ISO/IAF Action Plan

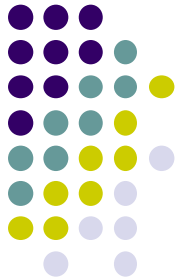


- Developed by IAF/ILAC/ISO Joint Working Group
- Key elements
  - Recognition that ***"OUTPUT MATTERS"***
    - Is the management system delivering on its promise?
  - Need for CB's to focus on "the clients' customers"
    - Are they satisfied with their supplier's ***performance***?
  - Need for a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

Some key developments…….

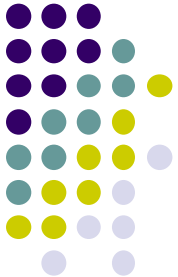
- ISO/IEC 17021 published in 2006
  - Requirements for CB's
  - Principles-based approach
  - Systematic approach to managing conflicts of interest
  - Two-stage initial audit required
- ISO/IEC 17021 Part 2 to be published in 2010
  - More focus on audit process and auditor competence

Some key developments (Cont…….)



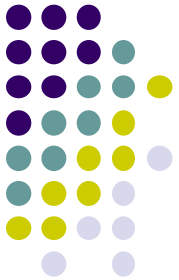
- Joint ISO/IAF Communiqué (June 2009) *"Expected Outcomes from Accredited Certification to ISO 9001 and ISO 14001"*
- Update of joint ISO/IAF Document *"ISO 9001 – What does it mean in the supply chain?"*
- Joint ISO/IAF Guidance on *"Good Auditing Practice"*
  - Aimed at 3rd party auditors, but also useful for internal auditors!
  - Similar set of guidance for Accreditation Body Assessors
- All are available for ***free download*** from www.iso.org and/or www.iaf.nu
  - Aim is to communicate the message to ALL auditors in ALL accredited CB's WORLDWIDE

Expected outcomes for ISO 9001 certification (from the customers' perspective)



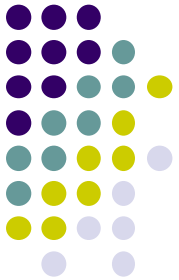
- ***"For the defined certification scope, an organization with a certified QMS consistently provides products that meet customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction."***

What this means..... (Summary)



- The organization ***has*** a QMS that conforms to applicable requirements of ISO 9001.
  - QMS is suitable for the organization's products and processes
  - Customer needs and expectations, and relevant statutory / regulatory requirements are understood
  - Product characteristics have been specified
  - Processes needed to achieve conforming products are managed
  - Necessary resources are available
  - Product characteristics are monitored and controlled
  - Focus on preventing NC's , with systematic improvement processes to
    - Correct any nonconformities that do occur
    - Analyze cause of nonconformities and take corrective action
    - Address customer complaints
  - Effective internal audit and management review
  - Monitoring, measuring and continually improving the QMS effectiveness

What accredited certification to ISO 9001 *does not* mean



- ISO 9001 defines requirements for an organization's ***QMS***, not for its products.
  - Certification ***does not*** necessarily ensure the organization will always achieve 100% product conformity, though this should of course be a permanent goal.
- Certification ***does not*** imply a superior product, or that the product itself is certified.

Expected outcomes for ISO 14001 certification (from the perspective of interested parties)

- ***"For the defined certification scope, an organization with a certified EMS is managing its interactions with the environment and is demonstrating its commitment to:***

  A. Preventing pollution.

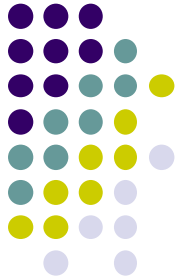
  B. Meeting applicable legal and other requirements.

  C. Continually enhancing its EMS in order to achieve improvements in overall environmental performance."

What this means..... (Summary)

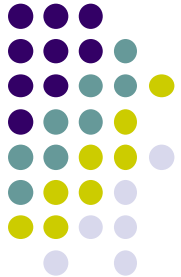
- The organization ***has*** an EMS that conforms to applicable requirements of ISO 14001.
  - Defined environmental policy appropriate to the nature, scale and impact of its activities, products and services
  - Identified environmental aspects that it can control and /or influence and determined those that can have a significant environmental impact (including those related to suppliers / contractors).
  - Identified applicable environmental legislation and other relevant requirements
  - Measurable environmental objectives and targets and programmes to achieve these
  - Ensures awareness and competence of people
  - Internal and external communication
  - Etc

What accredited certification to ISO 14001 *does not* mean



- ISO 14001 defines requirements for EMS but ***does not*** define specific environmental performance criteria.
- Certification ***does not*** ensure optimal environmental performance.
- The certification process ***does not*** include a full regulatory compliance audit and cannot ensure that violations of legal requirements will never occur, though full legal compliance should always be the organization's goal.
- Certification to ISO 14001 ***does not*** necessarily indicate that the organization will be able to prevent environmental accidents from occurring

Promoting feedback from purchasers…



- "ISO 9001 – What does it mean in the Supply Chain?"
  - Aims to educate purchasers about what they can reasonably expect from ISO 9000-certified suppliers
  - Explains about concepts of self-declaration, certification and accreditation
  - Encourages feedback
- Available on ISO website www.iso.org

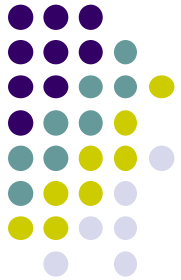
Explore further

ISO 9001:2000 – What does it mean in the supply chain?

Introduction

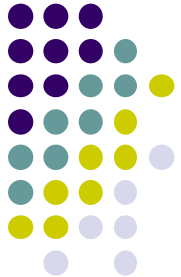
As someone who is involved in the selection of suppliers, and possibly responsible for purchasing decisions, you may have seen or used goods and services that are promoted using reference to ISO 9001:2000, or, more simply "ISO 9000". What does this mean? How can this help you? How can you be sure that your suppliers understand what you expect from them, and are capable of providing you with a consistent, conforming product? This information brochure provides some answers to these questions, and will inform you about how you can get the most out of using ISO 9001:2000 as a supply chain tool.

Some key developments (Cont…….)



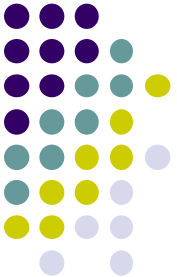
- IAF Mandatory Documents published, including:
  - Audit duration
  - Multiple (and temporary) sites
  - Transfer of certification
- IAF Guidance Documents published, including:
  - “Cross-frontier accreditation” – aimed at better collaboration between AB’s
- New IAF End-user committee established (2008)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

Some key developments (Cont…….)



- Joint CB-25/Inmetro Guidance for selection of
  - Consultants
  - Training organizations
  - Certification Bodies
- Currently being updated

Some key developments (Cont…….)

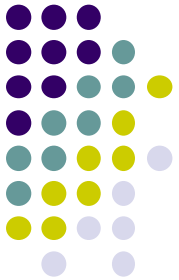


- IAF Task Groups working on following topics:
  - “Harmonization of Sanctions”
  - “Accreditation Market surveillance of certified organizations”
  - Use of CB performance indicators (“Metrics”)
  - End-user feedback
  - Competence criteria for AB Assessors (“JTA”)
  - Management of certification during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

Indian experiences……..

- "Validation visits" by Quality Council of India
  - Identification of fraudulent practices
    - Auditors reporting multiple audits (different cities!) on same day
    - Technical experts mentioned in reports but not participating in audit
  - Identical internal audit reports (templates from consultants!)
- Analysis of trends in audit results and effects of witnessing. For example (based on a number of cases)…..
  - Initial audit – 1 or 2 minor NC's; resolved and recommendation made for certification
  - 1st surveillance audit – no NC's; 1 or 2 OFI's – "continue certification"
  - 2nd surveillance audit (***WITNESSED!***) – Major NC's identified; numerous Minor NC's - certification suspended or withdrawn!!

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

- 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!")
- We ***ALL*** have an important role to play
- ***I continue to be optimistic!***

THANK YOU!

Questions?

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