

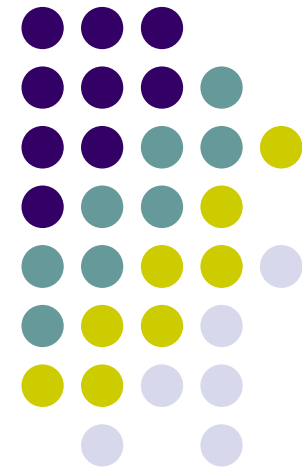
ISO 9001:2008

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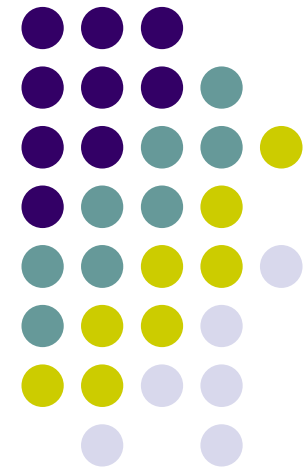
Member, “ISO/TC176 Strategic Advisory Group”, and “Project Oversight Task Group for ISO 9001:2008”

ISO/TC176 Liaison Representative to ISO/CASCO



Part 1

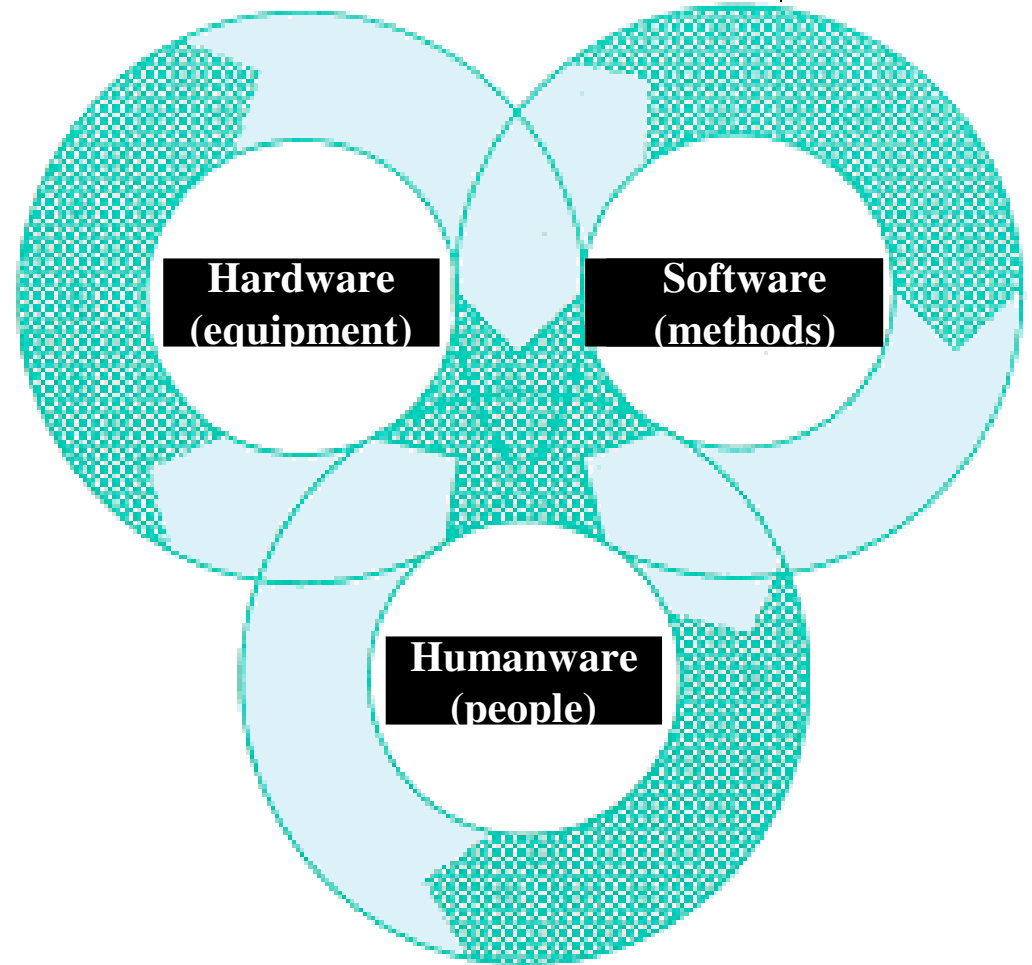
Management systems and the ISO Standards Development Process



What is a Management System?



- ISO 9000:2000 definition:
“set of interrelated or interacting elements to ***establish policy and objectives*** and to ***achieve those objectives***”



Management system should be *performance-based*



Example (ISO 9001:2000)

- Clause 1.1 - “Specifies quality management system requirements for organization to:
 - *demonstrate ability to consistently provide product that meets customer and applicable regulatory requirements*
 -enhance customer satisfaction”
- ISO 14001 and OHSAS 18001 have similar *performance-based* objectives



ISO/TC176

- “ISO” = International Organization for Standardization
 - Confederation of National Standards Bodies
 - Based in Geneva
- “TC176” = Technical Committee Number 176
 - Quality management and Quality Assurance

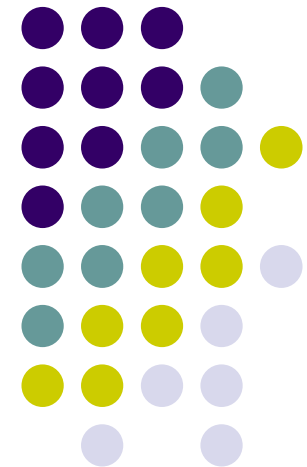


Overall Scenario of TC176

- Generic QMS standards have broad application:
 - all market sectors
 - both private and public organizations
- +/- 1,000,000 worldwide certifications to ISO 9001
- Many sector-specific standards based on ISO 9001:
 - ISO/TS 16949 (Automotive)
 - ISO 22000 (Food Safety)
 - TL 9000 (Telecom)
 - etc

Part 2

Changes to the ISO 9000 Standards



Rationale for new updates.....



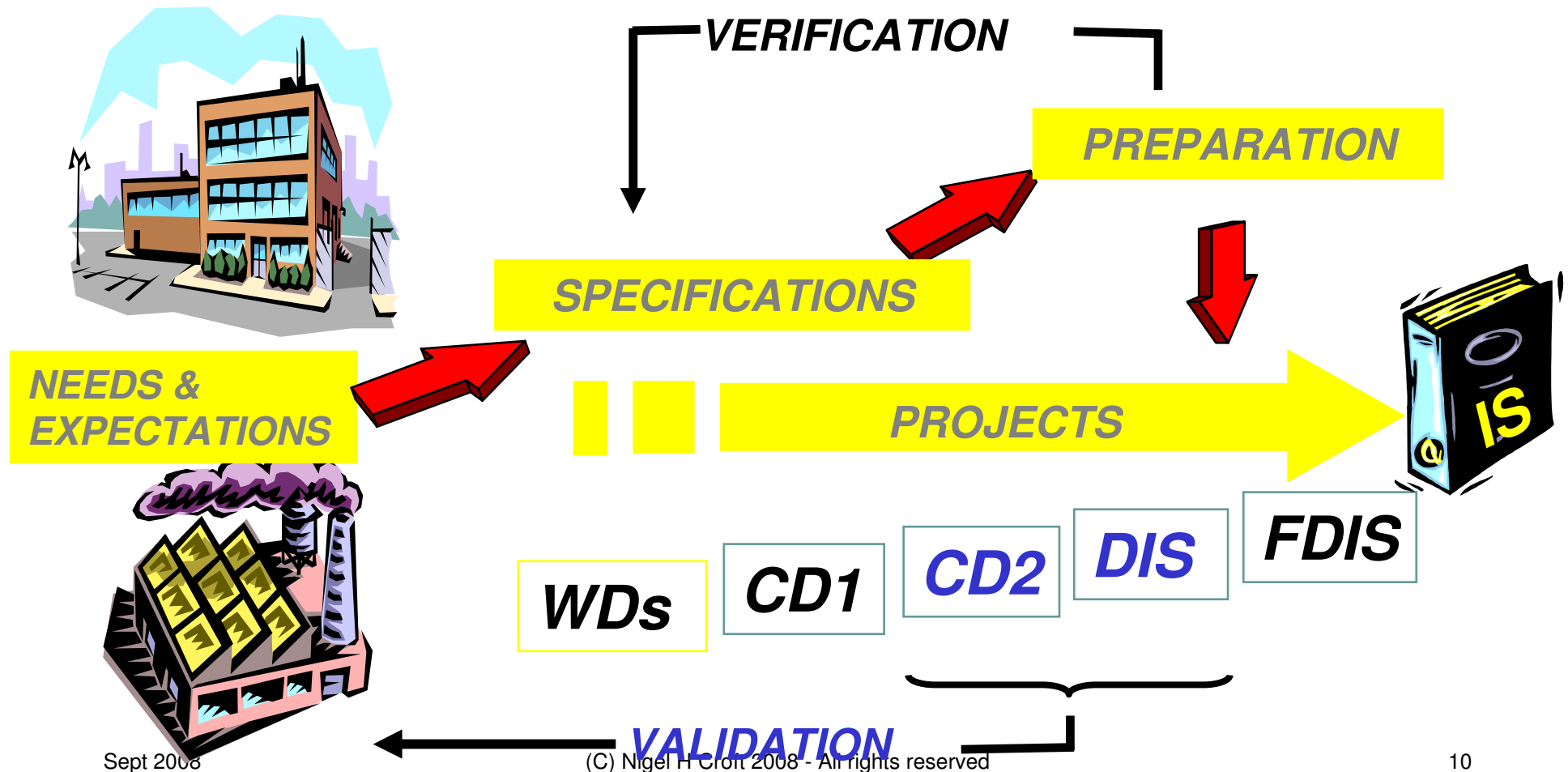
- ISO Review process:
 - Requires continual review (every 5 years) to keep standards up to date.
- User inputs:
 - User questionnaire
 - Suggestions arising from the interpretation process.
 - Opportunities for increased compatibility with ISO 14001
- Current trends:
 - Keeping up with recent developments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

The Global Challenges....



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

The standards development process



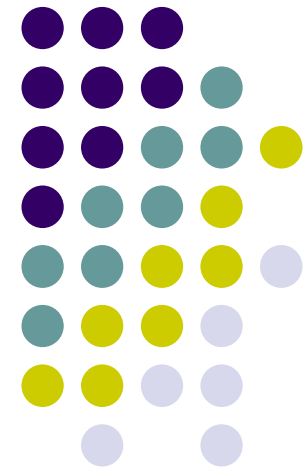
Next generation of “ISO 9000”



- ISO 9000:2005 already published – no major changes expected for 2008/2009
- Small changes to ISO 9001 (“amendment”)
 - ISO 9001:2008 now at FDIS stage – due for publication Nov 2008
- More significant changes to ISO 9004 (“revision”)
 - Currently at DIS stage – due for publication late 2009

Part 3

ISO 9001:2008





ISO 9001

- Initial objectives of ISO 9001:2008:
 - to improve the existing standard;
 - to provide greater clarity and ease of use,
 - to improve compatibility with ISO 14001:2004

Key inputs for ISO 9001:2008



- ISO/TC 176 approved interpretations
- The ISO 9001:2000 Introduction & Support Package set of documents
- Web based User Feedback Survey conducted by ISO/TC 176/SC2
- ISO 14001:2004



Interpretations Process

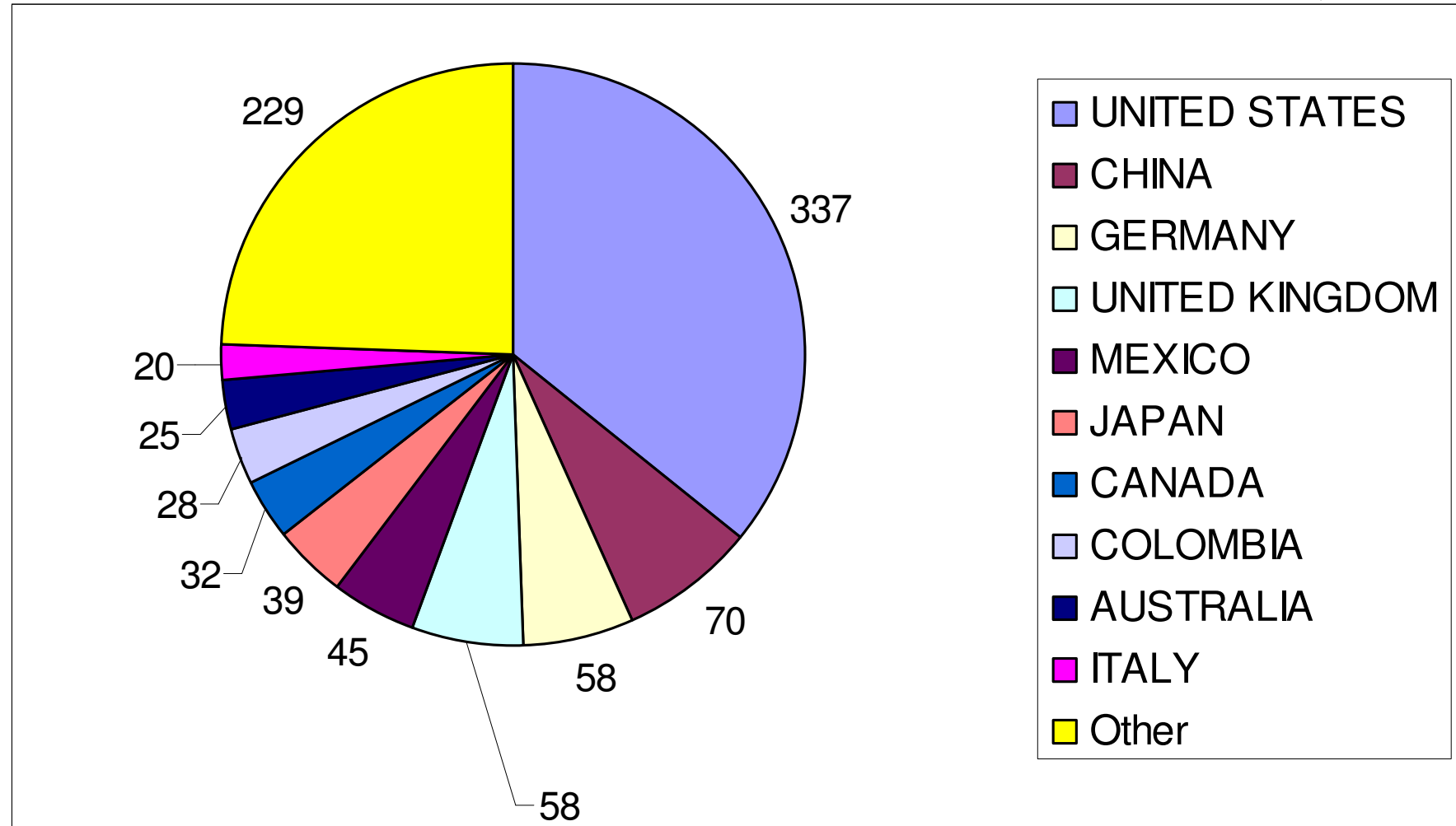
- 33 Official TC176 Interpretations published on ISO website
 - See www.tc176.org/ for details
- Important source of input for ISO 9001:2008
 - Some interpretation requests indicate need for clarification

Results of User Survey (2003)



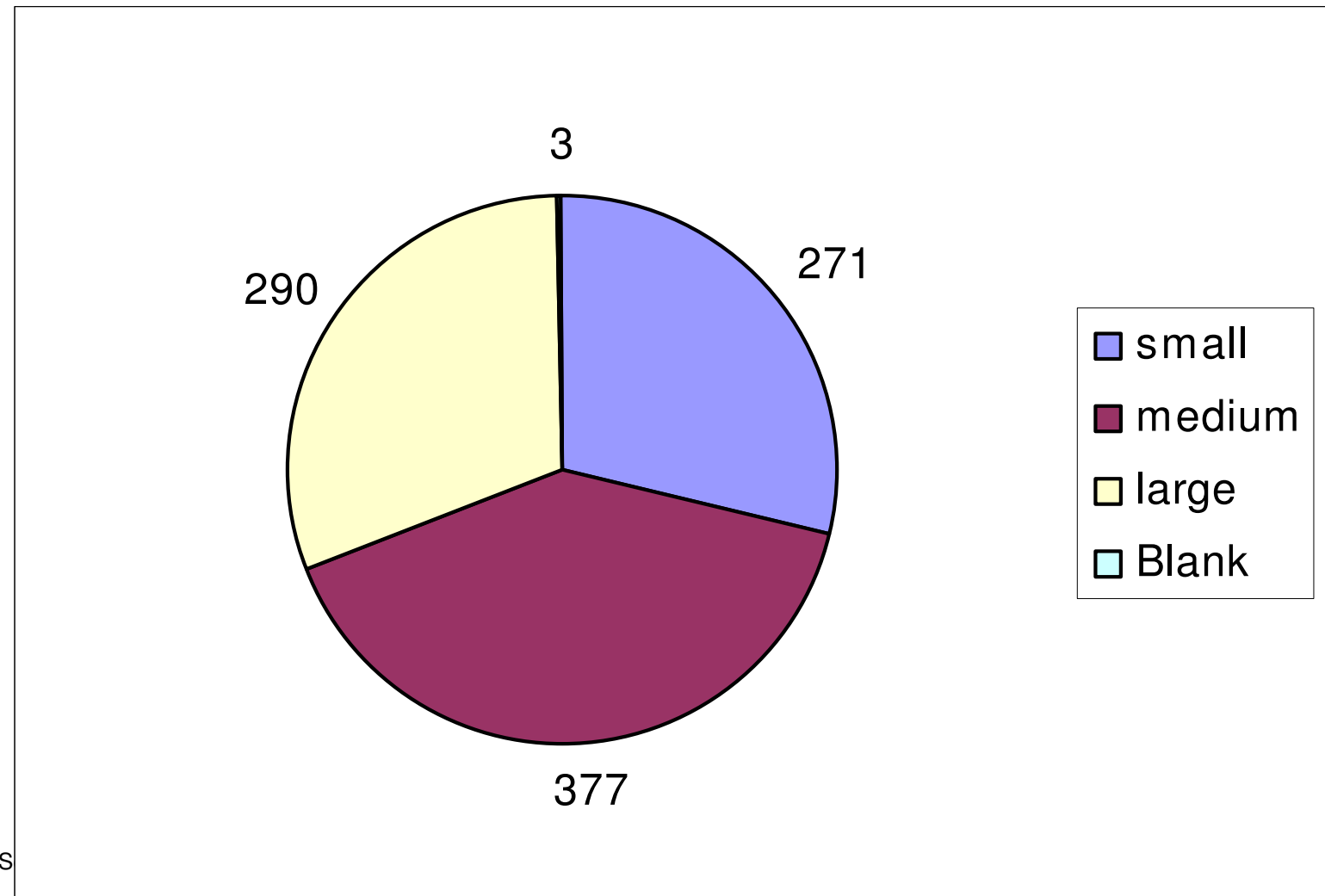
- Responses from 941 users in 63 countries.
- 1477 individual comments
- All four ISO 9001:2000 product categories (Hardware, Software, Processed Materials and Services) well represented.
- Approx 80% of respondents were satisfied with the ISO 9001:2000 standard.

Survey responses



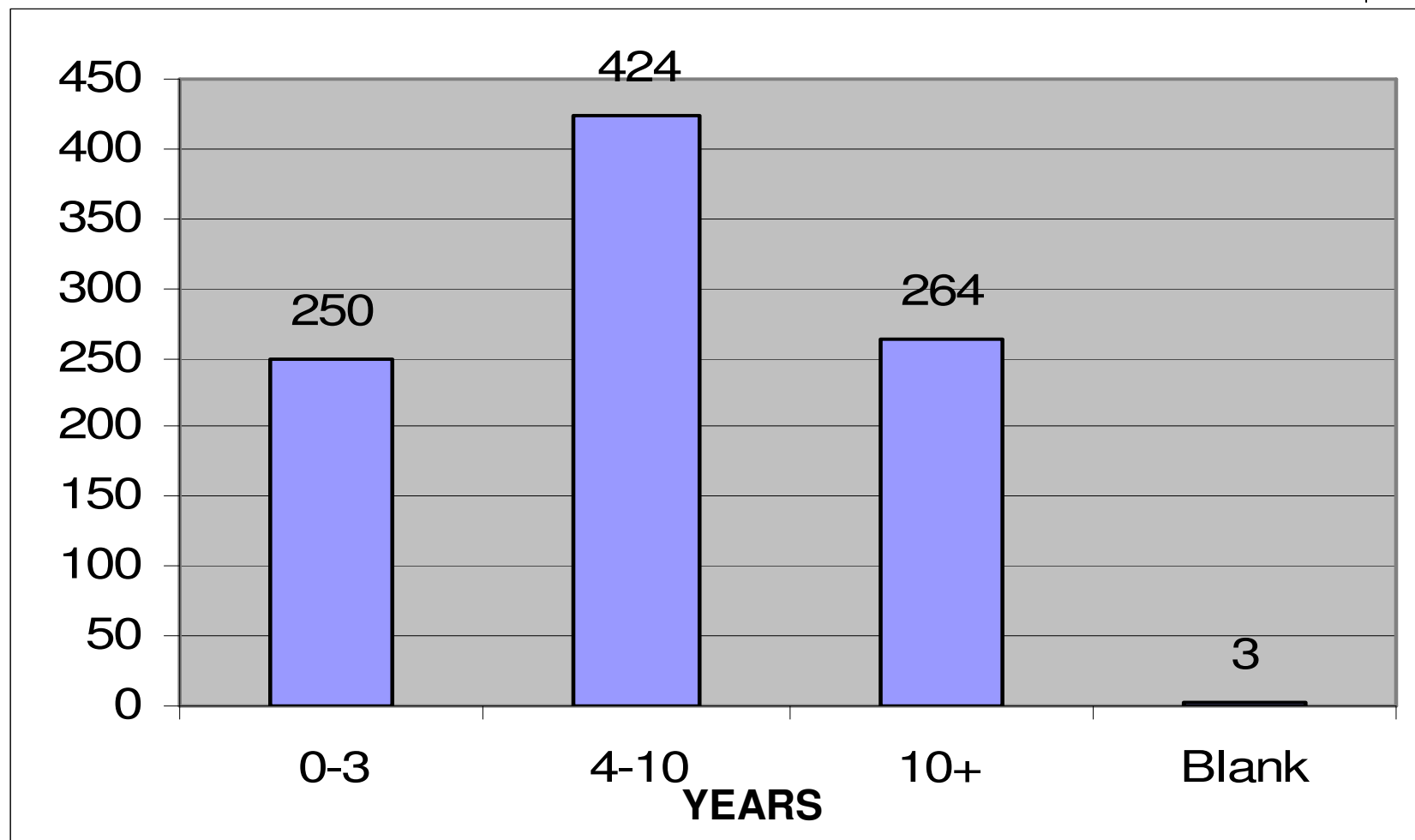


Size of organization

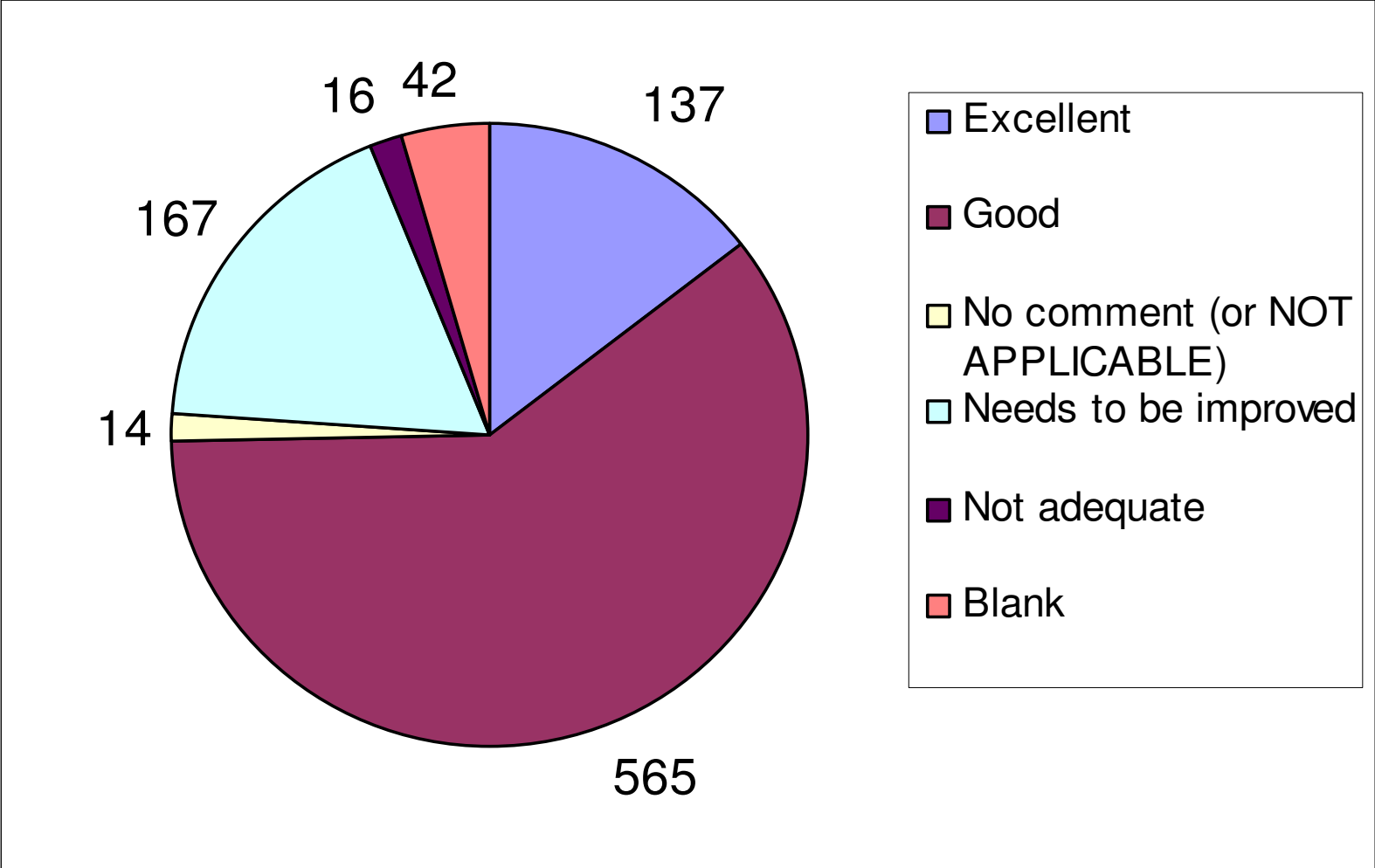
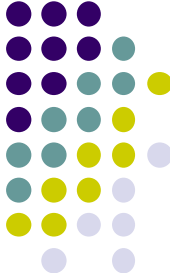




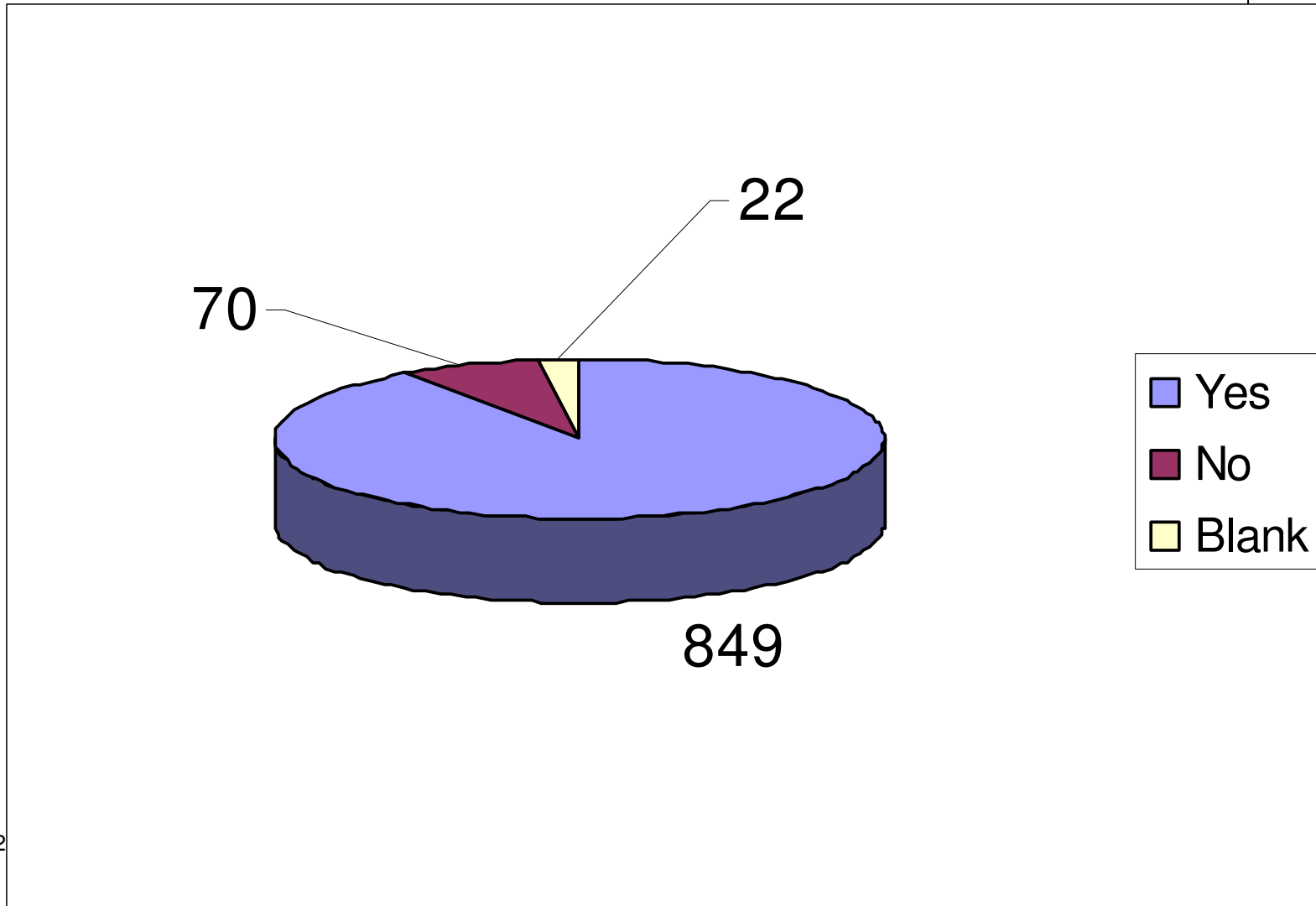
How long certified?



How well does ISO 9001:2000 meet your needs?



Are you happy with the process approach?



Most commented clauses / areas of confusion.....



813 (55%) of total 1477 comments related to:

- 4.1 General requirements
- 4.2 Documentation
- 6.2 Human resources
- 7.3 Design and development
- 7.5 Production and Service Provision
- 8.2 Monitoring and Measurement
- 8.5 Improvement



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 of changes to ISO 9001



Impact Category	Criteria
High	<ul style="list-style-type: none"> ▪ Additional or reduced requirements significantly affecting many users ▪ Change in intent of requirement ▪ Need for urgent revision of related QMS standards ▪ Need for extensive changes of an organization's documentation ▪ Decreased compatibility with ISO 14001 ▪ Inconsistency within the ISO 9000 family ▪ Need for recertification or significant transition period ▪ Need for extensive user education or training
Medium	<ul style="list-style-type: none"> ▪ Minor additional or reduced requirements for some users ▪ Possible impact on understanding by many users ▪ Need for limited changes of an organizations QMS documentation ▪ Need for eventual revision of other QMS standards ▪ No significant need for additional education or training for users ▪ Creates a minimal requirement for recertification or transition period
Low	<ul style="list-style-type: none"> ▪ No increased or reduced requirement ▪ No change in intent of requirement ▪ No impact on most users ▪ No need for additional education or training for users ▪ Only need for minimal or marginal changes of an organization's documentation

Benefits of changes to ISO 9001



Benefit Category	Criteria
High	<ul style="list-style-type: none"> • Addresses a widely expressed specific user need by improving clarity and eliminating confusion • Corrects an error in the existing standard • Eliminates inconsistencies within ISO 9001 • Eliminates inconsistencies within the ISO 9000 family • Eliminates major problems of translation
Medium	<ul style="list-style-type: none"> • Improves clarity in regard to a widely expressed user need but may not eliminate confusion and/or translation difficulty • Improves clarity in response to needs identified by some users • Increases compatibility with ISO 14001 • Demonstrates willingness to respond to the wish to see improvement in compatibility between ISO 9001 and ISO 14001 even though alignment is not a priority for this amendment • Reduces problems of translation
Low	<ul style="list-style-type: none"> • Improves clarity only in response to low number of requests for improvement • Marginal improvement in clarity where benefit may be offset by risk of unintended consequences, e.g. with respect to translation, interpretation • Changes not addressing a clear user need



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. <i>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 .</i>

Main changes introduced (based on “FDIS”)



- Clause 0.1 (General)
 - Introduces concept of organization’s business environment and associated risks.
- Clause 0.2 (Process Approach)
 - More emphasis on **output** from processes
- Clause 1.1 (Scope)
 - Clarification that “product” also includes intermediate product
 - Explanation regarding statutory, regulatory and legal requirements

Main changes introduced (based on “FDIS”)



- Clause 4.1 (General requirements)
 - Recognition that it might not always be possible to measure processes (clause 4.1 e), - addition of “***measure, where applicable***”
 - Notes added to explain more about outsourcing, based on the ISO 9001:2000 Guidance Documents.
 - Types of control that may be applied
 - Relationship to clause 7.4 (Purchasing)
 - Clarification that outsourced processes are still responsibility of the organization and must be included in the QMS

Main changes introduced (based on “FDIS”)



- Clause 4.2.1 (Documentation)
 - Clarification that QMS documentation also includes records
 - Documents required by the standard may be combined
 - ISO 9001 requirements may be covered by more than one documented procedure
- Clause 4.2.3 (Document Control)
 - Clarification that only external documents relevant to the QMS need to be controlled

Main changes introduced (based on “FDIS”)



- Clause 4.2.4 (Records Control)
 - Editorial changes only (better alignment with ISO 14001)
- Clause 5.5.2 (Management Rep)
 - Clarifies that this must be a member of the organization’s own management
- Clause 6.2.1 (Human resources)
 - Clarification that conformity to product requirements can be affected directly or indirectly by personnel performing any task within the QMS.

Main changes introduced (based on “FDIS”)



- Clause 6.2.2 (Competence, training and awareness)
 - Clause title changed for better alignment with ISO 14001
 - Clause 6.2.2 (b) changed to read *“Where applicable,the organization shall..... provide training or take other actions **to achieve the necessary competence**”*
- Clause 6.3 (Infrastructure)
 - Includes information systems as example
- Clause 6.4 (Work environment)
 - Clarifies that this includes conditions under which work is performed and includes, for example physical, environmental and other factors such as noise, temperature, humidity, lighting, or weather

Main changes introduced (based on “FDIS”)



- Clause 7.2.1 (Customer related processes)
 - Clarifies that post-delivery activities may include:
 - actions under warranty provisions
 - contractual obligations such as maintenance services
 - supplementary services such as recycling or final disposal

Main changes introduced (based on “FDIS”)



- Clause 7.3.1 (Design & development planning)
 - Clarifies that design and development review, verification and validation have distinct purposes.
 - These may be conducted and recorded separately or in any combination as suitable for the product and the organization
- Clause 7.3.3 (Design & development outputs)
 - Clarifies that information needed for production and service provision includes preservation of the product

Main changes introduced (based on “FDIS”)



- Clause 7.5.3 (Identification and traceability)
 - Clarifies that identification of product status must be maintained throughout product realization
- Clause 7.5.4 (Customer property)
 - Explains that both intellectual property and personal data should be considered as customer property

Main changes introduced (based on “FDIS”)



- **Clause 7.6 (Now retitled **Control of Monitoring and Measuring *equipment***)**
 - New explanatory note added:
 - “Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.”

Main changes introduced (based on “FDIS”)



- Clause 8.2.1 (Customer Satisfaction)
 - Note added to explain that monitoring of customer perception may include input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, dealer reports
- Clause 8.2.2 (Internal audit)
 - The standard now requires the area being audited to ensure that ***any necessary corrections and corrective actions*** are taken without undue delay.....

Main changes introduced (based on “FDIS”)



- Clause 8.2.3 (Monitoring / Measurement of process)
 - Note added to clarify that when deciding on appropriate methods, the organization should consider impact on the conformity to product requirements and on the effectiveness of the quality management system.

Main changes introduced (based on “FDIS”)



- Clause 8.5.2 (Corrective action)
 - Clause 8.5.2 (f) clarifies the need to review the **effectiveness** of corrective actions taken
- Clause 8.5.3 (Preventive action)
 - Clause 8.5.3 (f) clarifies the need to review the **effectiveness** of preventive actions taken

Table of changes to be made available.....

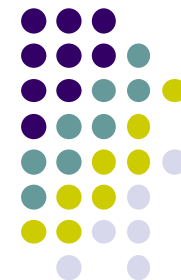


- [Changes table](#)
- Developed by TC176/SC2/WG18/TG1.22
- Will be available on www.iso.org

Implementation Policy (ISO / IAF)



- Before publication of ISO 9001:2008 – no accredited certificates to new standard allowed
- November 2008 – Publication of ISO 9001:2008
- Up to 1 year after publication – certification / renewal to ISO 9001:2000 still permitted
- Beginning 1 year after publication, no new certificates to ISO 9001:2000 allowed – all audits to be conducted to ISO 9001:2008
- 2 years after publication – ISO 9001:2000 certificates will no longer be valid

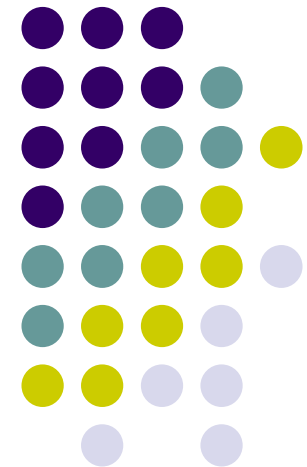


What should you do now?

- Review the changes and check how they apply to you
- If you find something that changes your understanding of the requirements, you might need to make small changes to your system
- When everything is OK, request next surveillance or recertification audit based on ISO 9001:2008
- **THERE'S NO IMMEDIATE RUSH!** The changes are small and you should have no problem to migrate to ISO 9001:2008 very quickly and at minimal cost

Part 4

A word about ISO 9004:2009



Rationale for major revision to ISO 9004



- Results of User survey
 - ISO 9004:2000 used very little
 - Level of satisfaction much lower than for ISO 9001
- Nigel Croft opinion of ISO 9004:2000
 - “Good standard for those who don’t need it”
 - “Poor standard for those who do need it”



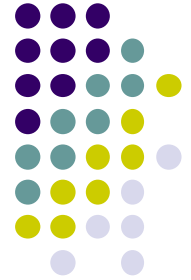
ISO 9004:2009....

- “Managing for the sustained success of an organization – A quality management approach”
- Aim is “To help organizations who are users of ISO 9001 obtain sustained benefit from the implementation of a more broad-based and in-depth quality management system”.

Some topics addressed in ISO 9004:2009



- Understanding organization's business environment and Critical Success Factors
- Strategic management
- Involvement and motivation of people
- Suppliers and partners
- Knowledge, information & technology management
- Natural resources and life-cycle management
- Measurement
 - Includes KPI's, self-assessment, benchmarking
- Improvement, innovation and learning



Schedule for ISO 9004

- ISO/DIS 9004:2000 currently being distributed for comment and ballot
- Likely publication date Sept 2009



Conclusions

- ISO 9001:2008 is scheduled for publication in Nov 2008
 - No major changes
 - No major impact
 - 2-year “transition”
- Major revision to ISO 9004 scheduled for 2009
 - “Sustained success of an organization”
- The ISO 9000 family continues to evolve.....

THANK YOU

Questions / Discussion

