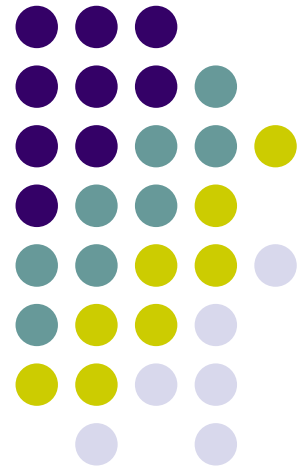
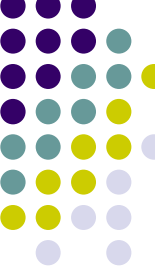


# The ISO 9000 Standards

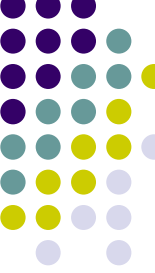
What's New for 2008/ 09?





# Contents

- Rationale for updates
- The ISO Standards development process
- Scope of changes
  - ISO 9001
  - ISO 9004

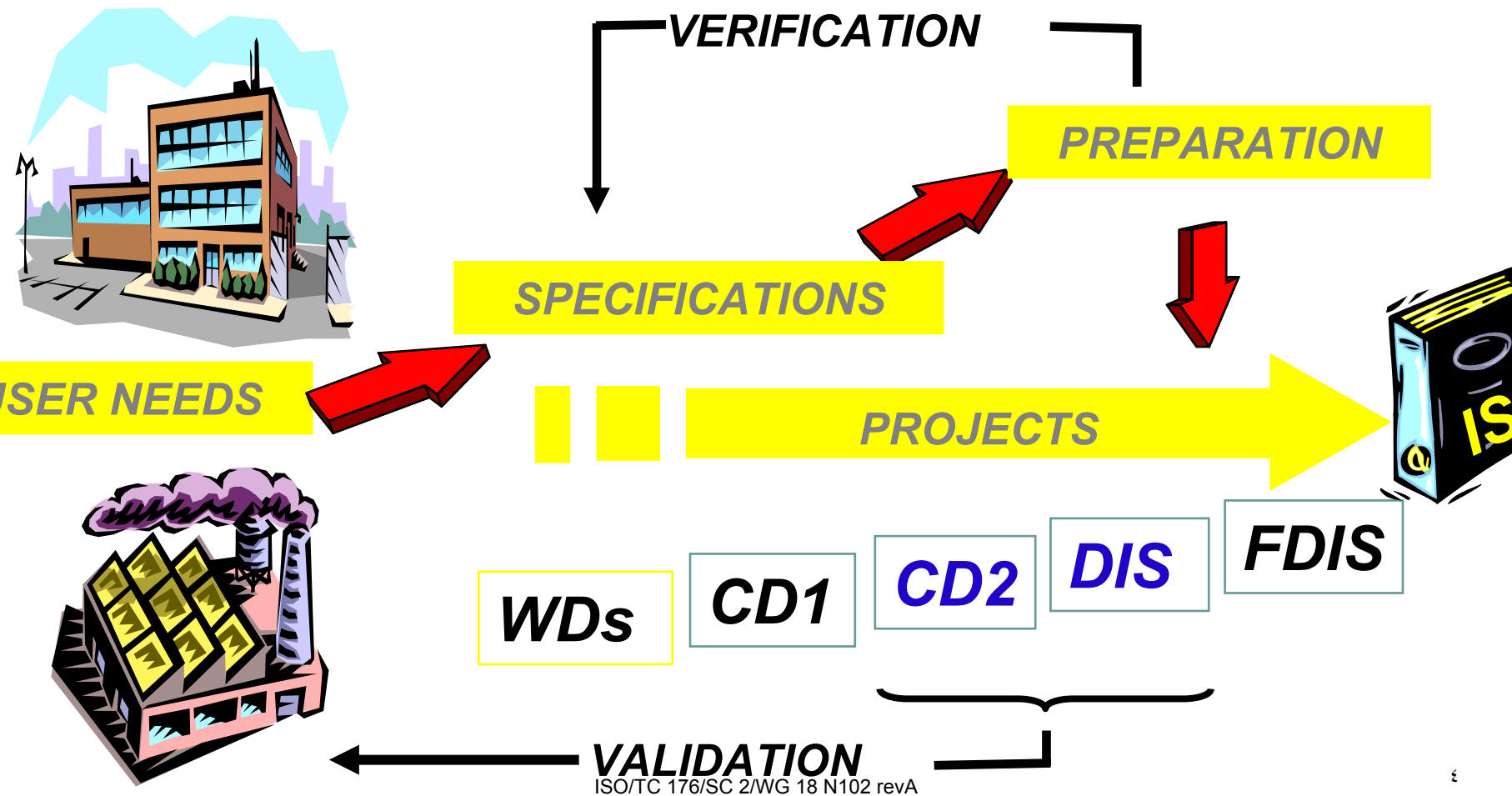


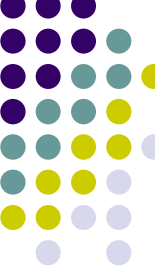
# Rationale for updates.....

- ISO Review process:
  - Requires continual review to keep standards up to date. Must be initiated within 5 years of publication of the standard.
- User inputs:
  - Global user questionnaire/survey
  - Market Justification Study
  - 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 ISO standards development process

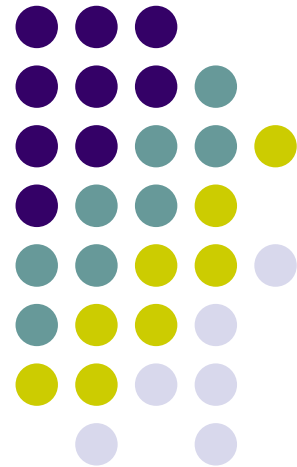




# Next generation of “ISO 9000”

- Summary:
  - ISO 9000:2005 already published – no major changes expected for 2009
  - Current plan is for small changes to ISO 9001 (“amendment”)
  - More significant changes to ISO 9004 (“revision”)
- Design specifications for ISO 9001 and ISO 9004 approved by ISO/TC176/SC2 in Sept 2005.
- Committee Drafts are currently being circulated for comment by ISO/TC176/SC2 members

# ISO 9001:2009





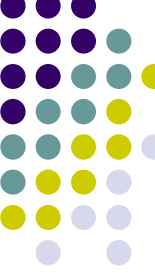
# ISO 9001

- Main objectives of ISO 9001:2009:
  - to provide greater clarity and ease of use
    - incorporate improvements to address the interpretations and clarifications requested by users through the ISO/TC176 Interpretations Process
  - to improve compatibility with ISO 14001:2004

# What do we mean by “Amendment” to ISO 9001?



- No formal ISO distinction between a “revision” and an “amendment”
- Aim is to emphasize that no MAJOR changes to the requirements are expected for ISO 9001
  - Focus is on changes that improve clarity, translatability, and ease of use; address ambiguities that resulted in requests for interpretations; improve consistency with the ISO 9000 Family, and improve compatibility with ISO 14001:2004,



# Impacts and benefits

- Amendment to ISO 9001 will focus on high benefit / low impact improvements
- Some high benefit / high impact improvements will be saved for the next revision cycle
- Criteria for assessing impact and benefit are shown in the following slides



# Key Inputs for the Amendment

- ISO/TC 176 approved interpretations,
- The ISO 9001:2000 Introduction & Support Package set of documents.
- Systematic Reviews conducted on ISO 9001:2000 and ISO 9004:2000
- Web based User Feedback Survey conducted by ISO/TC 176/SC2
- ISO 14001:2004,
- ISO Guide 72:2001, Guidelines for the justification and development of management system standards – Market Justification Study

# The ISO 9000:2000 Support Package / Guidance documents



- Documentation requirements
- The process approach
- Application of ISO 9001:2000 (“Permissible Exclusions”)
- Guidance on “Outsourcing”
- Available from [www.iso.org](http://www.iso.org)

# 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

# Key strategies for ISO 9001:2009.....



- ISO 9001:2000 Process Approach model will be maintained
- The standard will remain generic and be applicable to all sizes and types of organization operating in any sector.
- Compatibility with ISO 14001:2004 to be maintained and if possible enhanced
- Consistency with the revision of ISO 9004:2000 will be maintained
- Changes will be restricted to limit impact on users

# Key strategies for ISO 9001:2009..... (Continued)



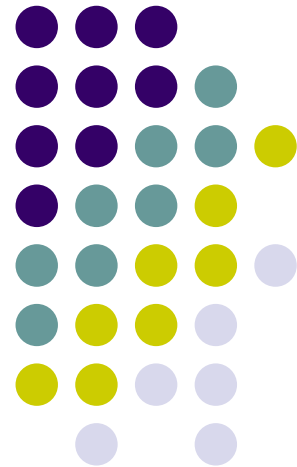
- The ISO 9001:2000 support package will be used to assist the writers to identify issues needing clarification.
- Ambiguities requiring formally produced interpretations will be addressed
- Changes only introduced where there are clear benefits
- Drafts of the amended standard will be subjected to verification against the design specification, and to validation by users

# Other decisions already made for ISO 9001:2009 .....



- The current scope, purpose, title and field of application of the standard will be unchanged.
- The 8 Quality Management Principles (as contained in ISO 9000:2005) will be applied, unchanged.

# ISO 9004:2009



# Purpose of ISO 9004:2009.....



- “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”.



# Objectives for ISO 9004:2009

- Facilitate improvement in users' quality management systems
- Provide guidance to an organization for the creation of a quality management system that:
  - creates value for its customers, via the products it provides
  - creates value for all other interested parties,
  - balances all interested-party viewpoints.
- Provide guidance for managers on leading their organization towards sustainable success.
- Forward compatibility to allow organizations to build on existing quality management systems.

# Target customers for ISO 9004:2009



- First Priority

- Current users of ISO 9001:
- Organizations just getting started on ISO 9001

- Second Priority

- Organizations who are not users of ISO 9001 who want to go farther in QMS implementation than 9001

# ISO 9004:2009 is *not* intended to be:



- An implementation guide to ISO 9001
- A business excellence model
- A set of requirements
- A textbook on Total Quality Management
- A source of untried approaches and methods

# “Guiding Principles” for ISO 9004:2009



- Continue to use the “eight Quality Management Principles”, but also take into account:
  - Ethics /social aspects
  - Mission and Vision of the organization
  - Adaptability / agility (ability to respond to changing opportunities / threats).
  - Management of knowledge.
  - Alignment with other management systems
  - Linking objectives and actions to results.

# THANK YOU

Questions?

