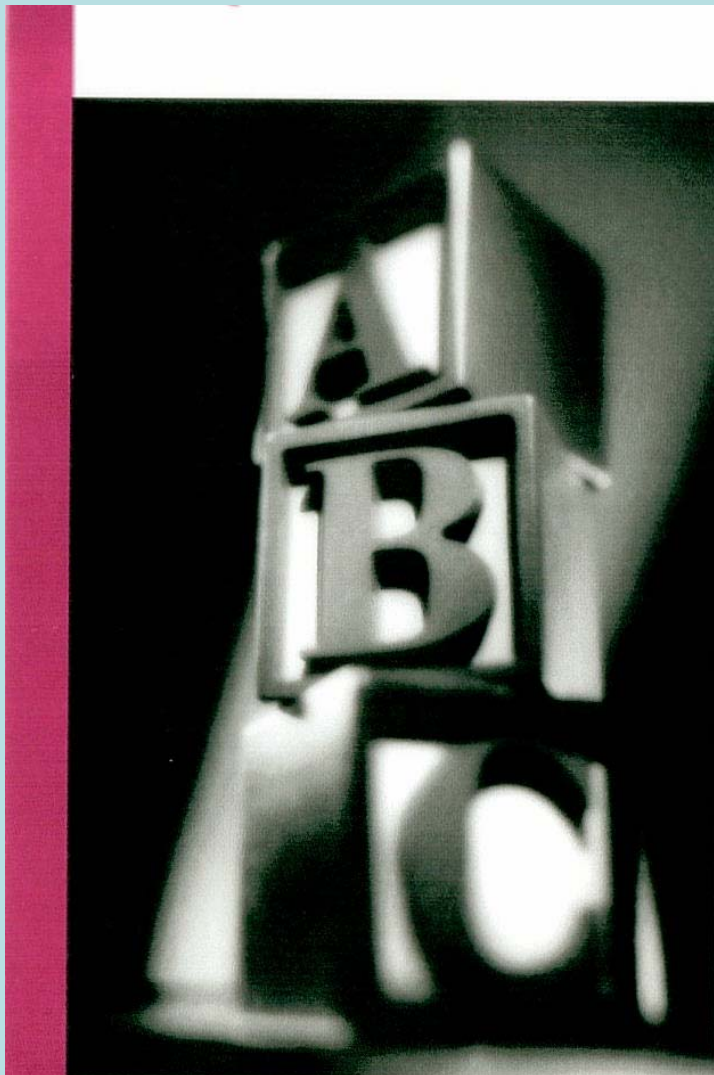




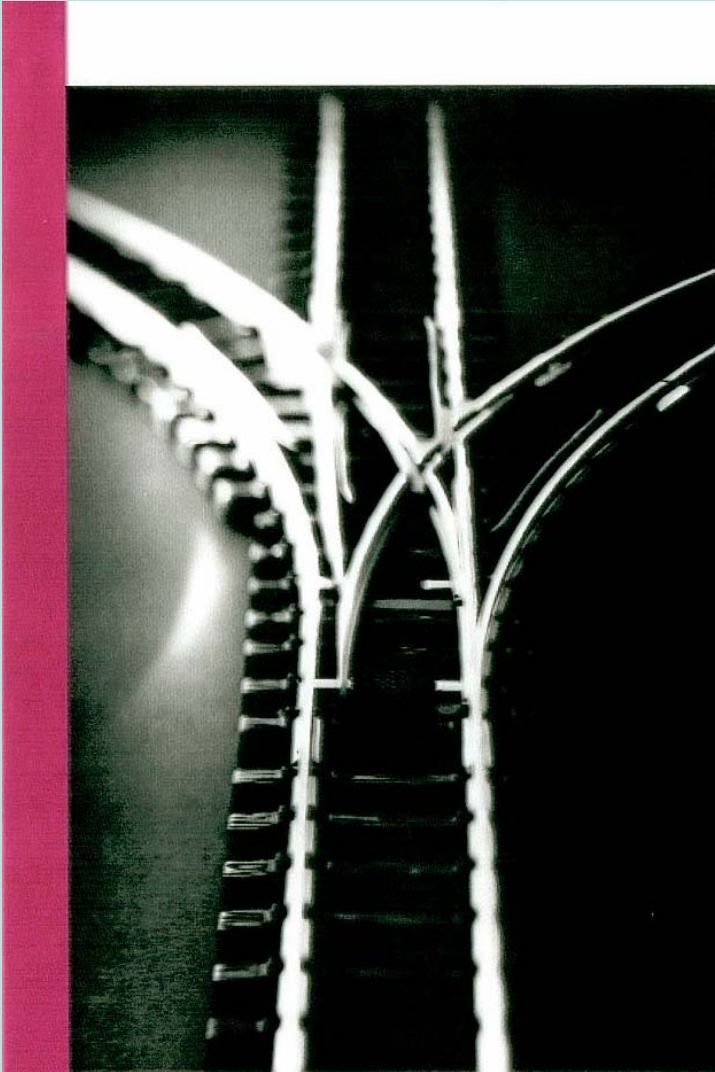
Deutsche Gesellschaft
für Qualität e.V.

Wie entstehen Normen? die Revision der ISO 9000-Familie

Regionalkreis Hamburg, 08. Mai 2007



- gemeinnützig und unabhängig seit 1952
- Wir informieren und qualifizieren in Qualitäts- und Umweltmanagement / Arbeitssicherheit (ca. 20.000 Teilnehmer im Jahr)
- Wir arbeiten aktiv in der internationalen Normung mit
- Wir regen zur interdisziplinärer wissenschaftlicher Forschung an
- Wir informieren über neueste Erkenntnisse aus den Bereichen Qualität, Umwelt, Arbeitssicherheit in Form von Fachliteratur, Tagungen und Workshops
- Wir sind nach DIN EN ISO 9001 zertifiziert und als Personalzertifizierer nach DIN EN 17024 akkreditiert



- Regionale Präsenz:
 - über 60 Regionalkreise bundesweit
 - vier Landesgeschäftsstellen(500 Veranstaltungen, 13.000 Teilnehmer)
- Gemeinschaftsarbeit:
Fachleute aus allen Wirtschaftszweigen engagieren sich in Arbeitsgruppen (über 70 Titel)
- Gründungs- und Vollmitglied der EOQ
 - international anerkannte Ausbildung (EOQ - Zertifikate)
- nationale Partnerorganisation der EFQM
- Ludwig-Erhard-Preis:
... für Spitzenleistung im Wettbewerb

- Ihre Erwartung an die Systemnormung
- Was kann Normung leisten?
- Stand der Systemnormung
- Organisation der internationalen Normung
- Aufbau des TC 176
- Aufbau des deutschen Spiegelgremiums
- Welche Dokumente werden einer Revision unterzogen?

Leicht umsetzbar

verständlich

Vielseitig anwendbar

praxisnah



unterstützend

problembezogen

konsistent

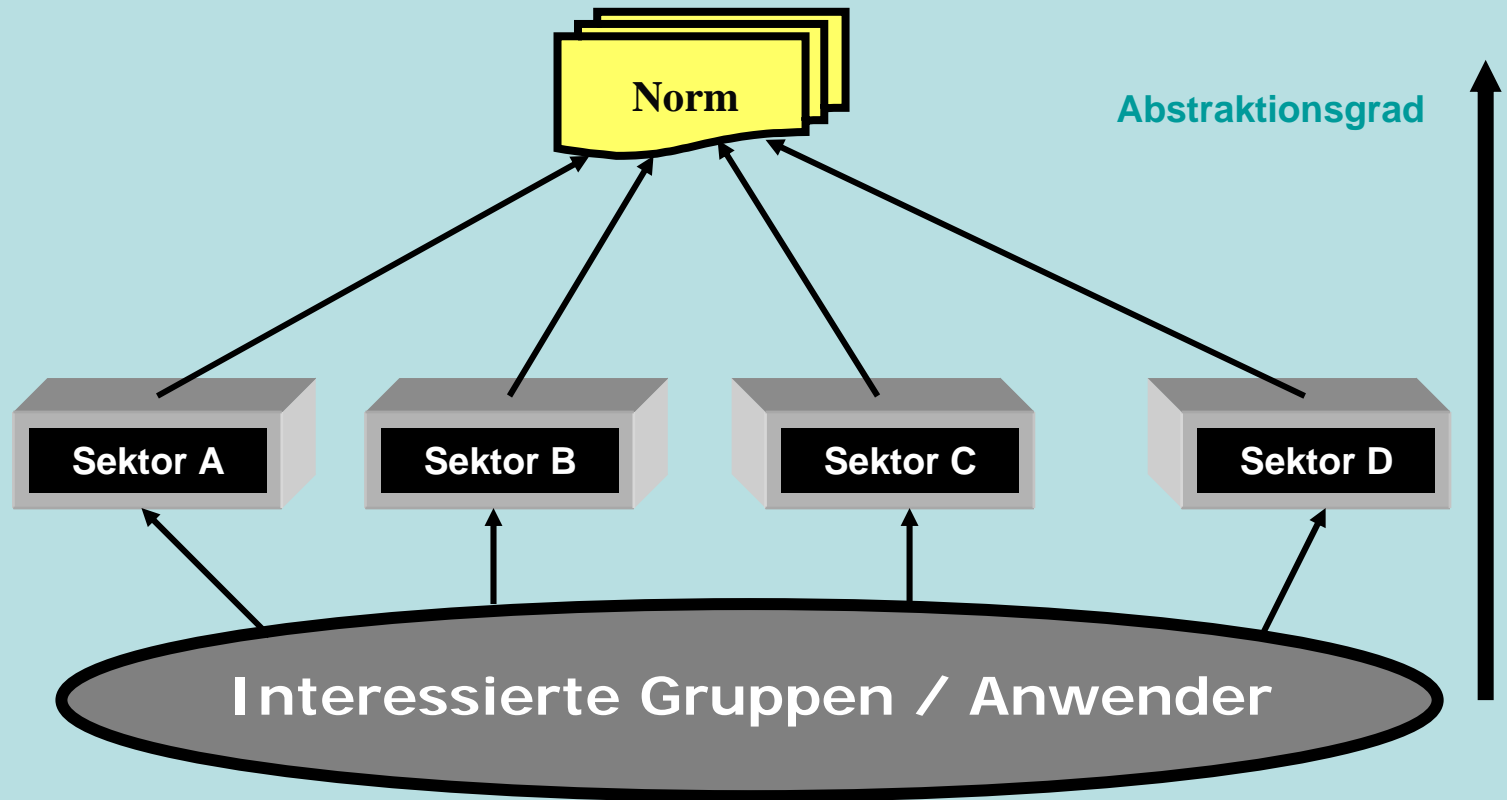
kohärent

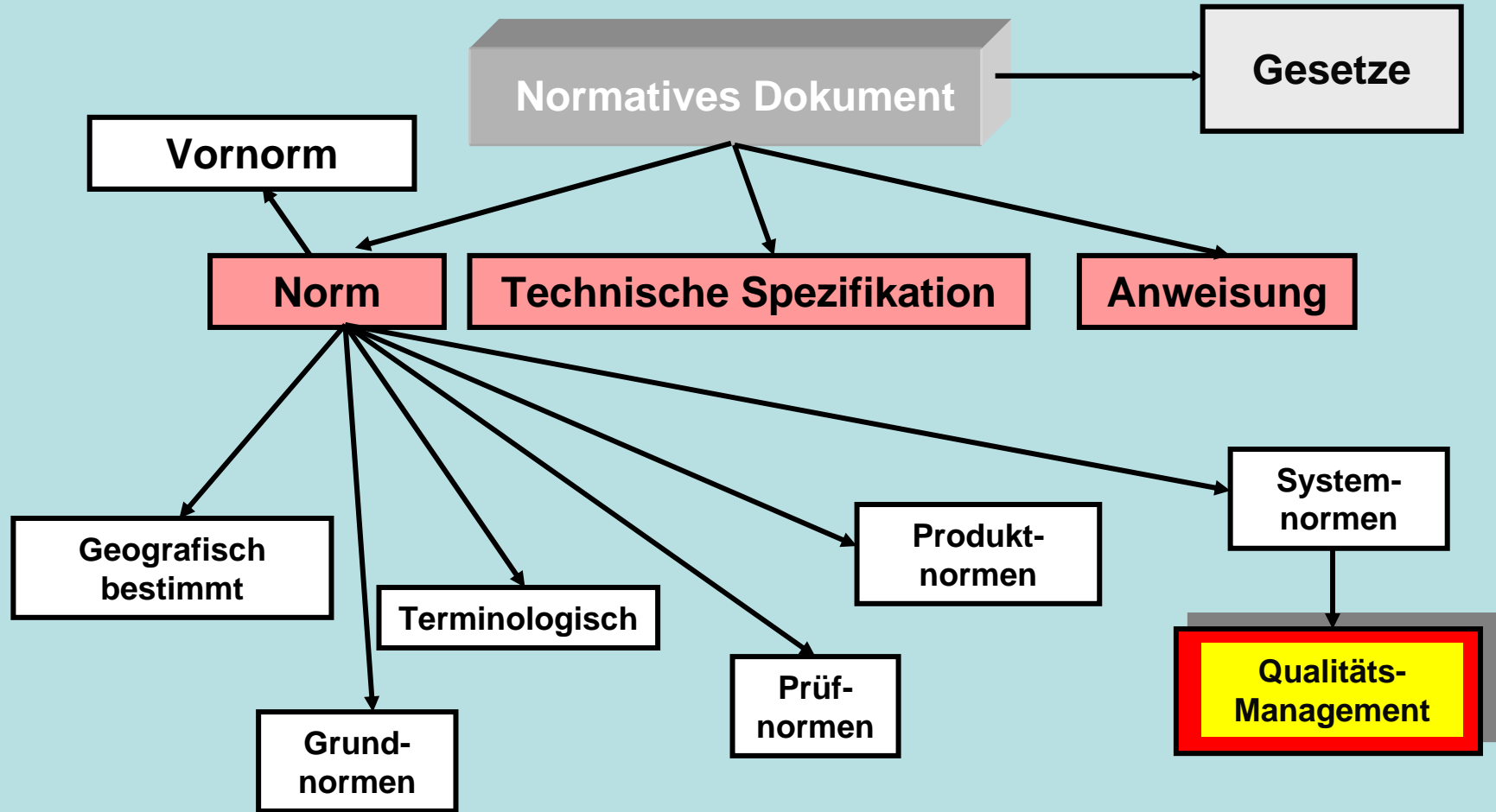
verfügbar

- **Prinzipien**

- **Geplante Vereinheitlichung von materiellen und nichtmateriellen Gegenständen zum Wohl der Gesellschaft, die durch die interessierten Kreise gemeinsam durchgeführt wird**
- **Normung darf nicht zu wirtschaftlichen Vorteilen für eine besondere Gruppe führen**
- **Sie soll die Rationalisierung und die Qualitätssicherung in allen Sektoren von Wirtschaft; Technik und Wissenschaft und Verwaltung fördern**

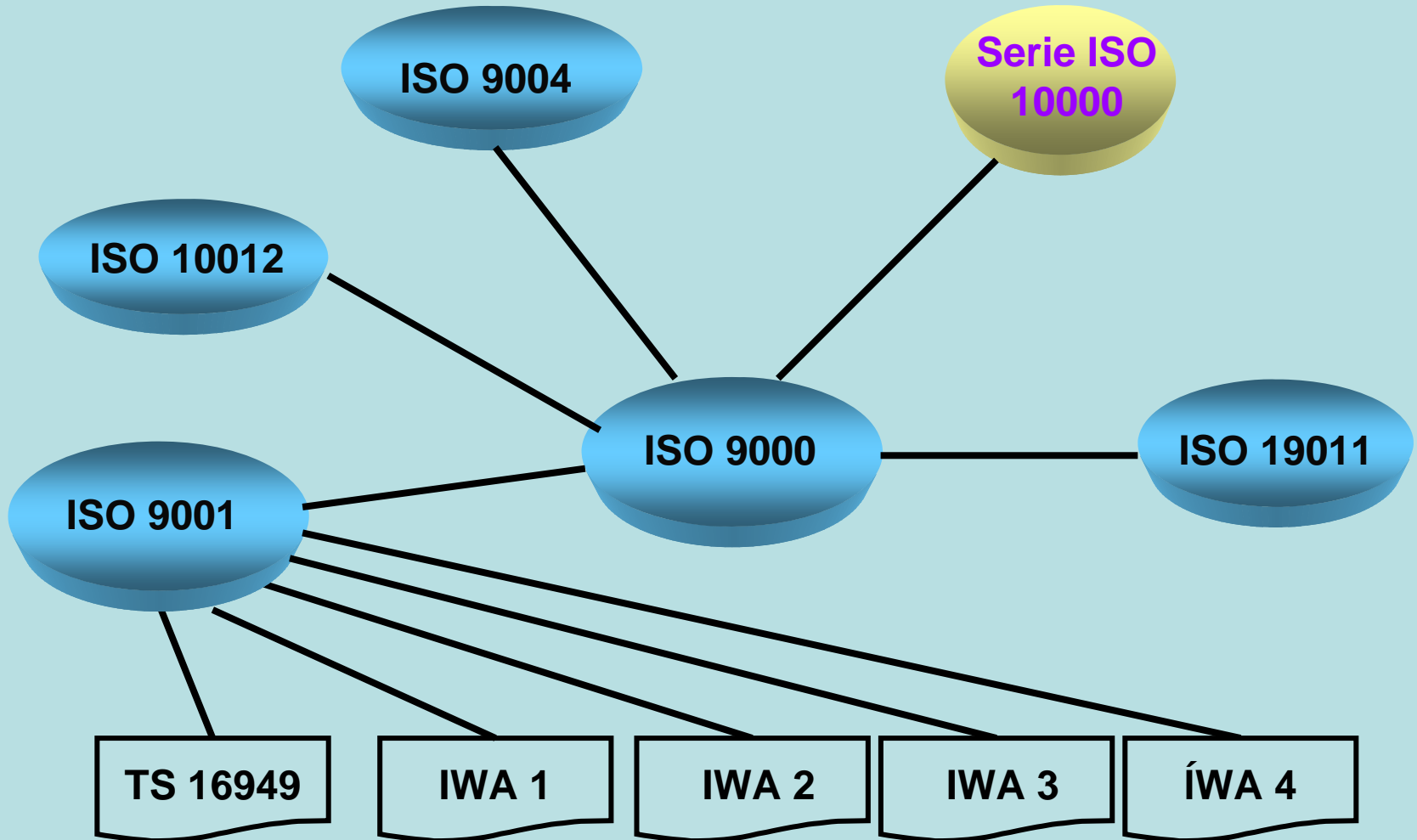
(nach DIN 820:94.04)

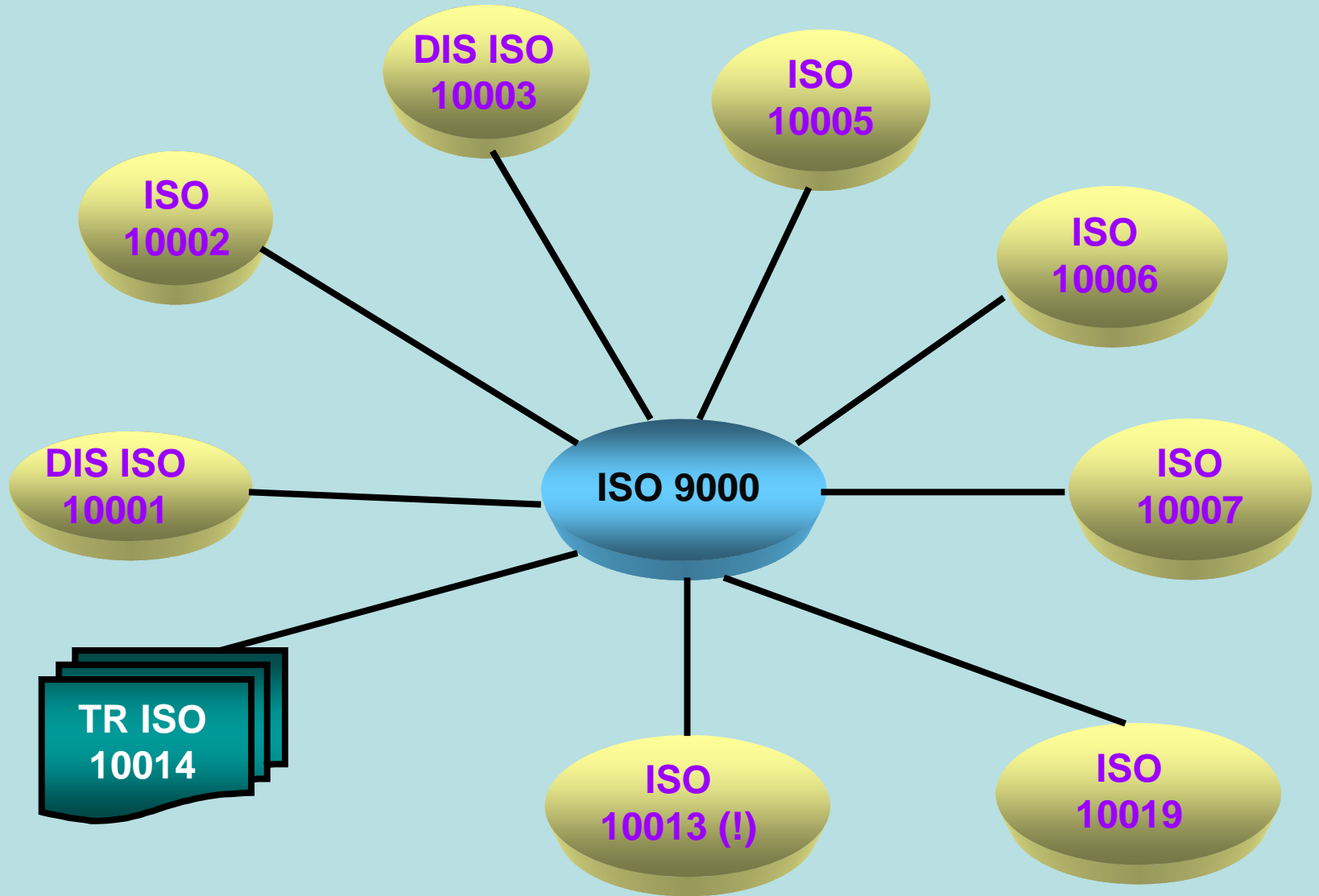


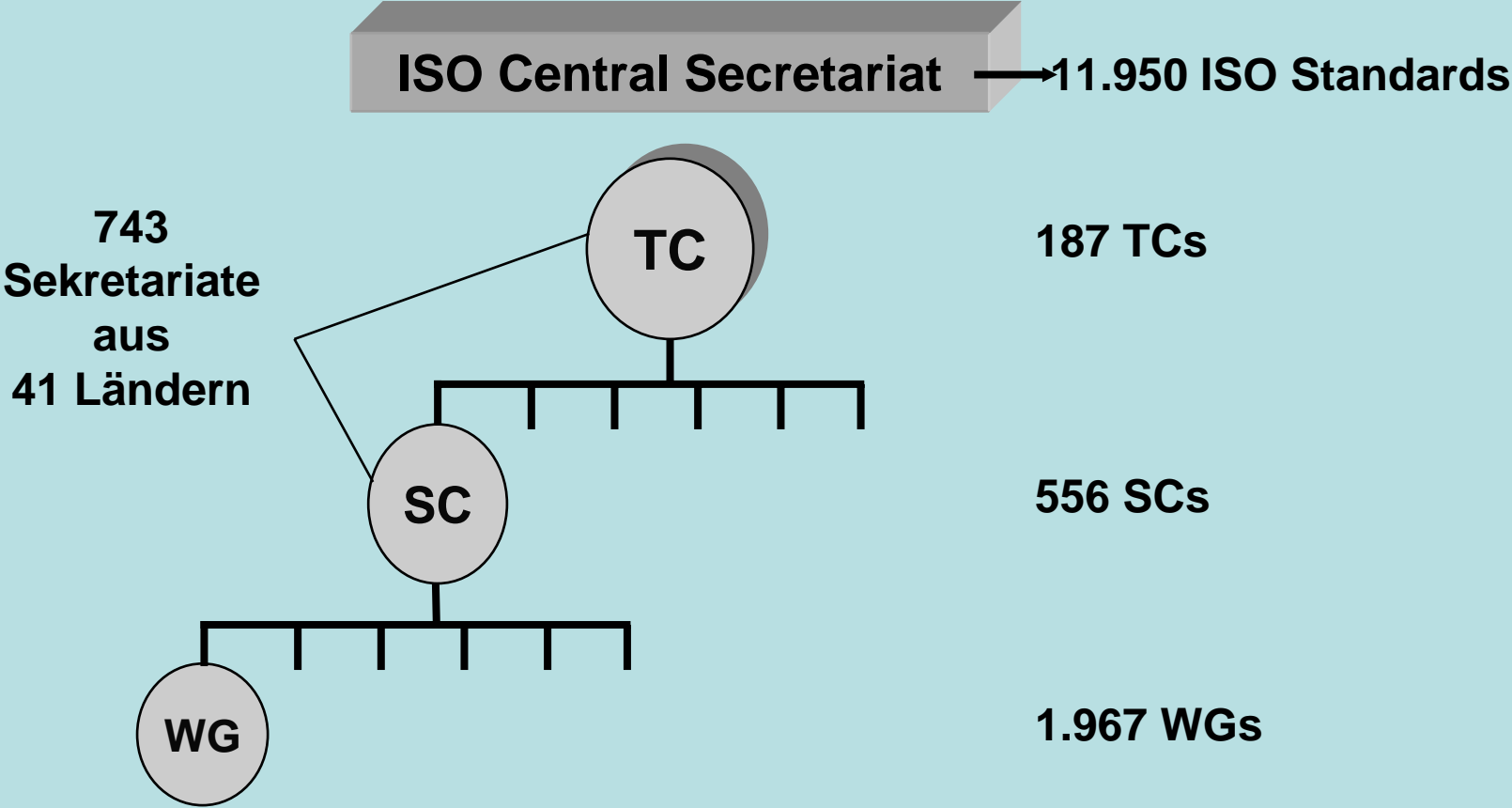


(DIN EN 45020:98.07)





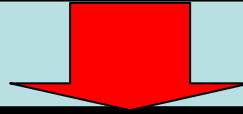




~ 7.000 Aktive Projekte

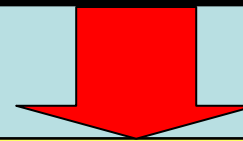
Den Anwendungsbereich eines TC festlegen

Es wird nur genormt, was sich in das Arbeitsgebiet eines TC einordnen lässt



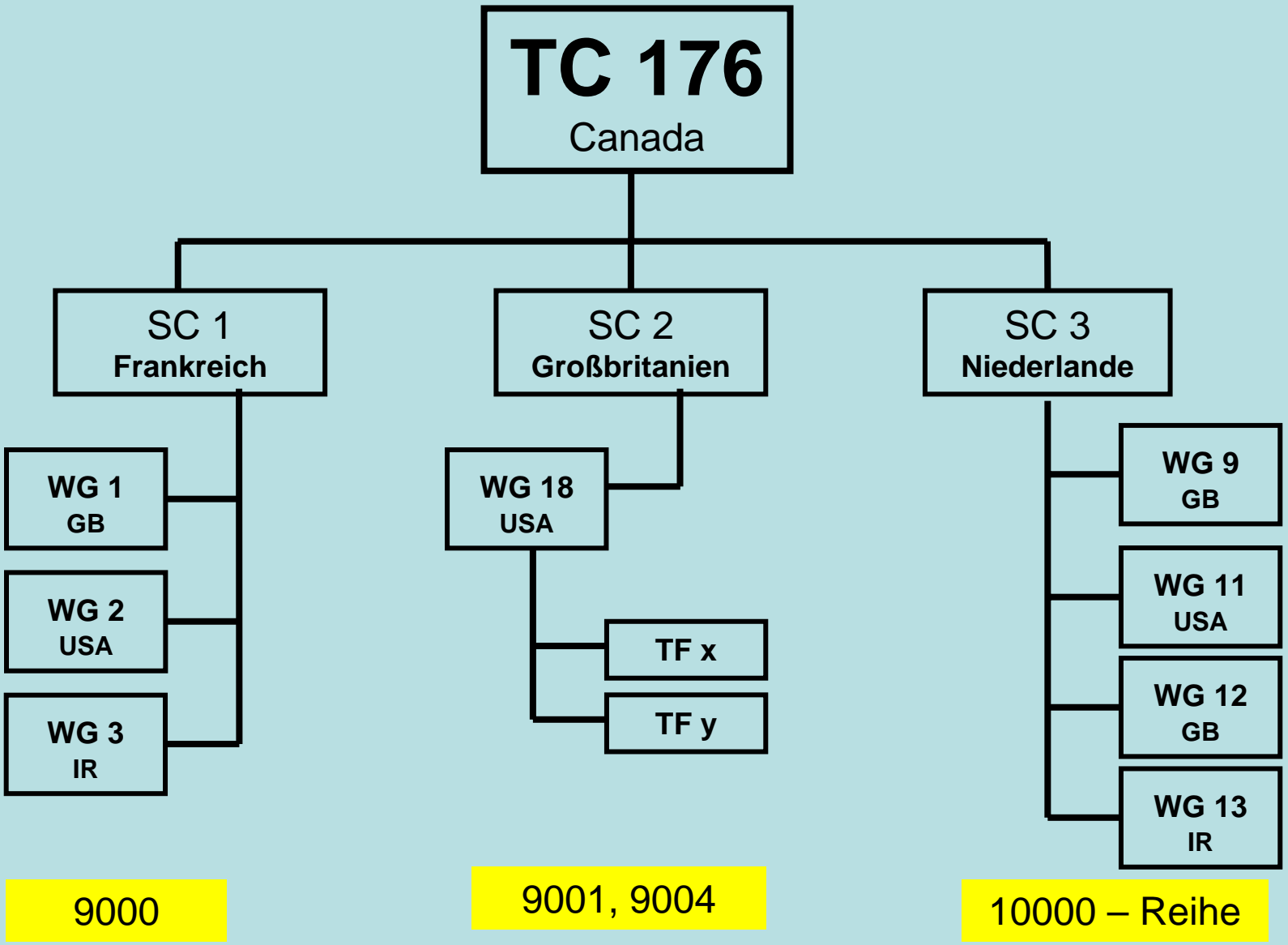
Die interessierte nationale Normenorganisation legt einen Vorschlag vor, der den Titel, den Anwendungsbereich, das Ziel, eine Begründung und einen Projektplan enthält (NWIP).

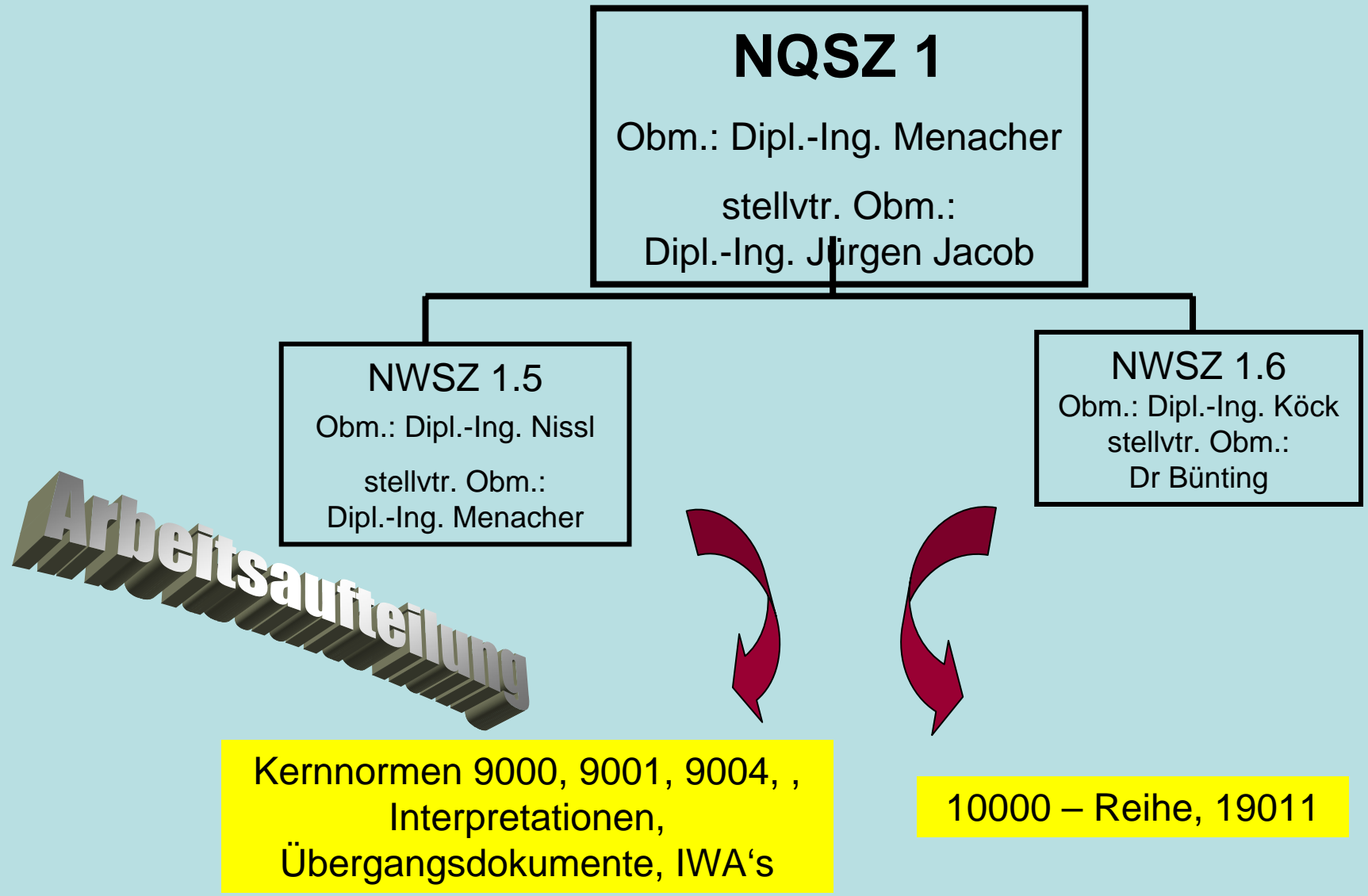
nur, wenn diese Voraussetzungen erfüllt sind, beginnt ein Normenprojekt



Die Vollmitglieder (FM) stimmen über das Projekt ab und bekunden ihre Bereitschaft, Experten zu entsenden.

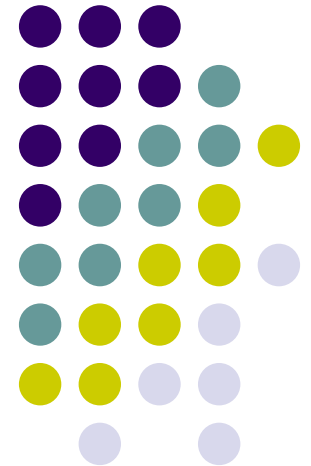
Nur die kontinuierliche Teilnahme bietet eine realistische Möglichkeit, das Endergebnis zu beeinflussen.





The ISO 9000 Standards

What's New for 2009?



Contents



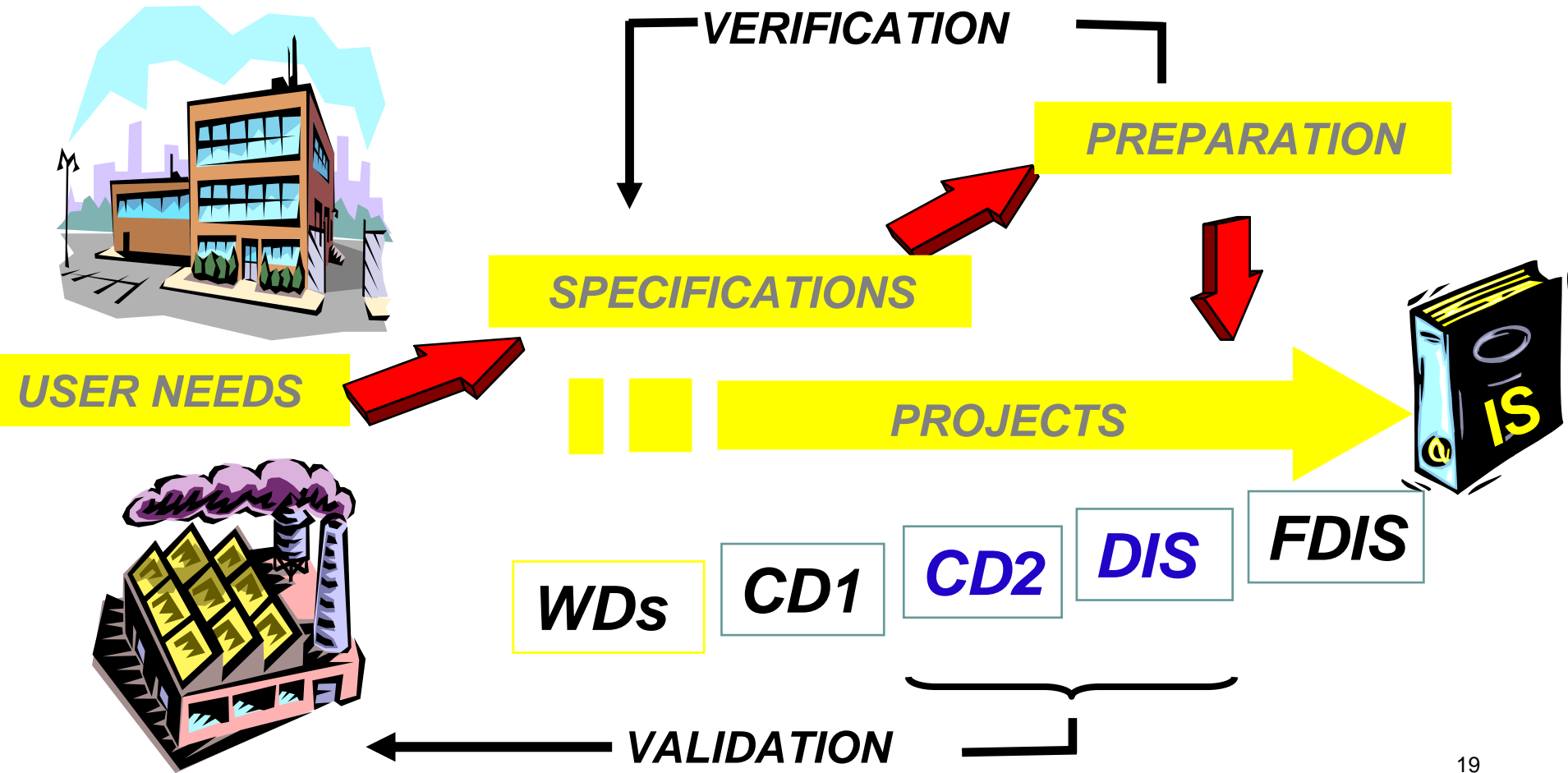
- Rationale for updates
- The ISO Standards development process
- Scope of changes
 - ISO 9001
 - ISO 9004
- Timetable
- Contact details

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

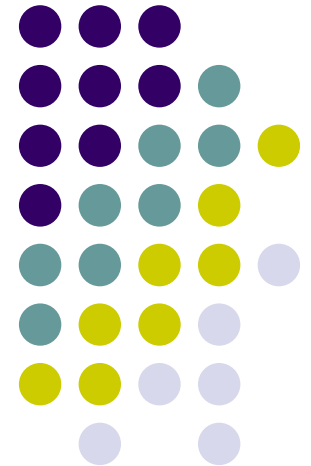


Next generation of “ISO 9000”



- 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 ...

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



Interpretations Process

- 37 Official TC176 Interpretations published on ISO website
 - See www.tc176.org/ for details
- Important source of input for ISO 9001:2009
 - Some interpretation requests indicate need for clarification

The ISO 9000:2000 Support Package / Guidance documents



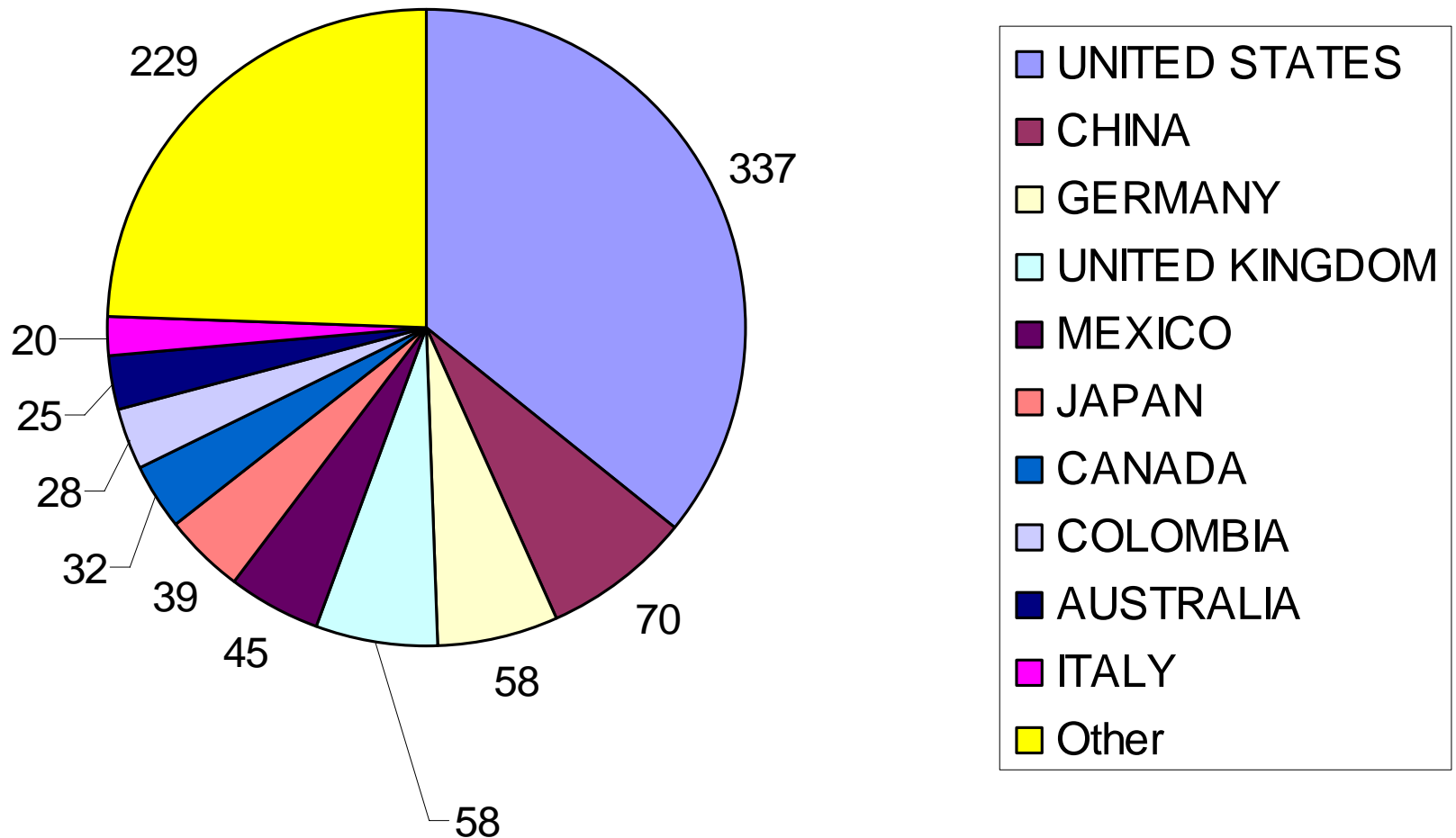
- Documentation requirements
- The process approach
- Application of ISO 9001:2000 (“Permissible Exclusions”)
- Guidance on “Outsourcing”
- Available from www.iso.org

Results of User Survey (2003)

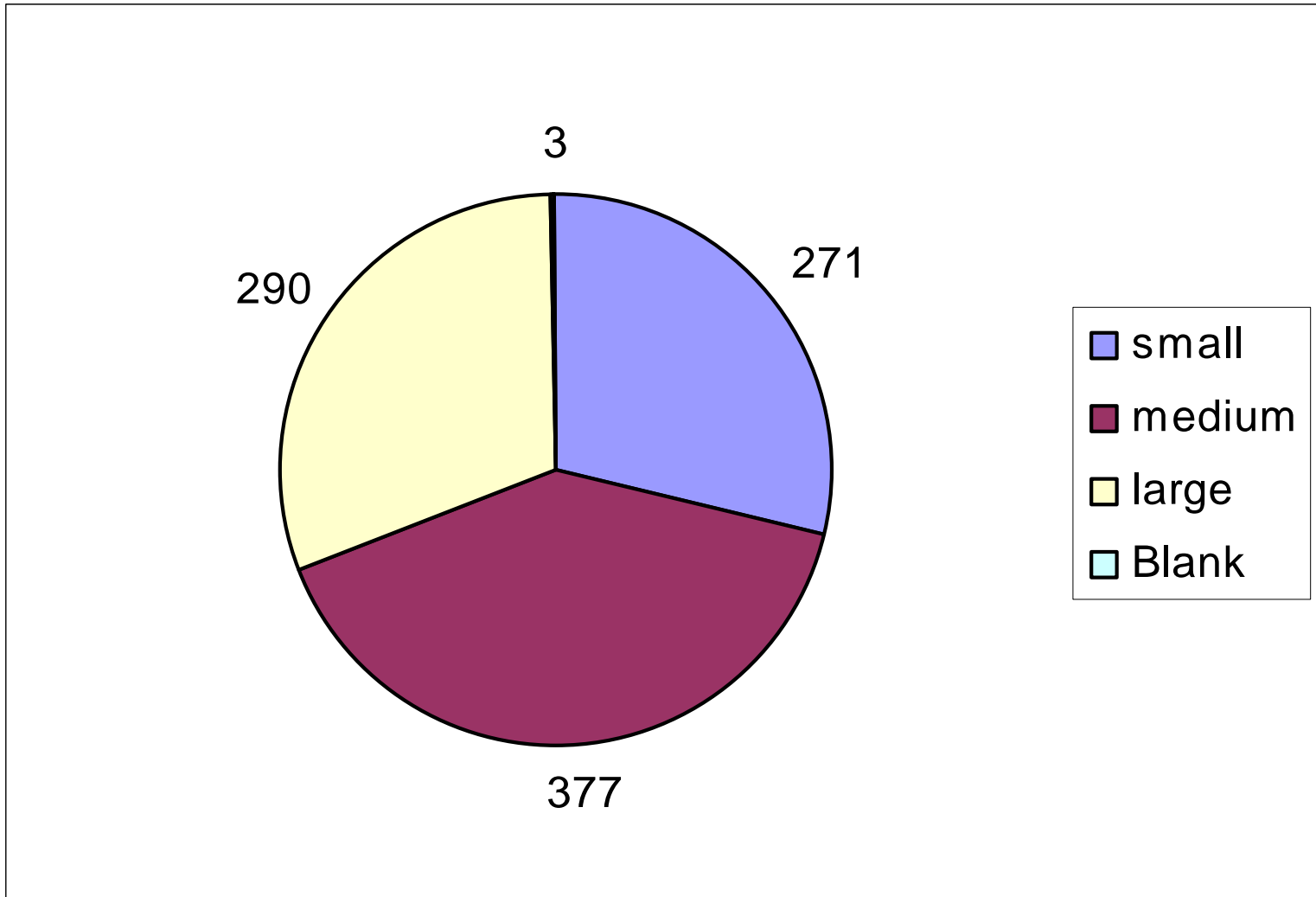


- Responses from 941 users in 63 countries.
- 1477 individual comments
- All four ISO 9001:2000 product categories (Hardware, Software, Processed Materials and Services) well represented.
- Approx 80% of respondents were satisfied with the ISO 9001:2000 standard.

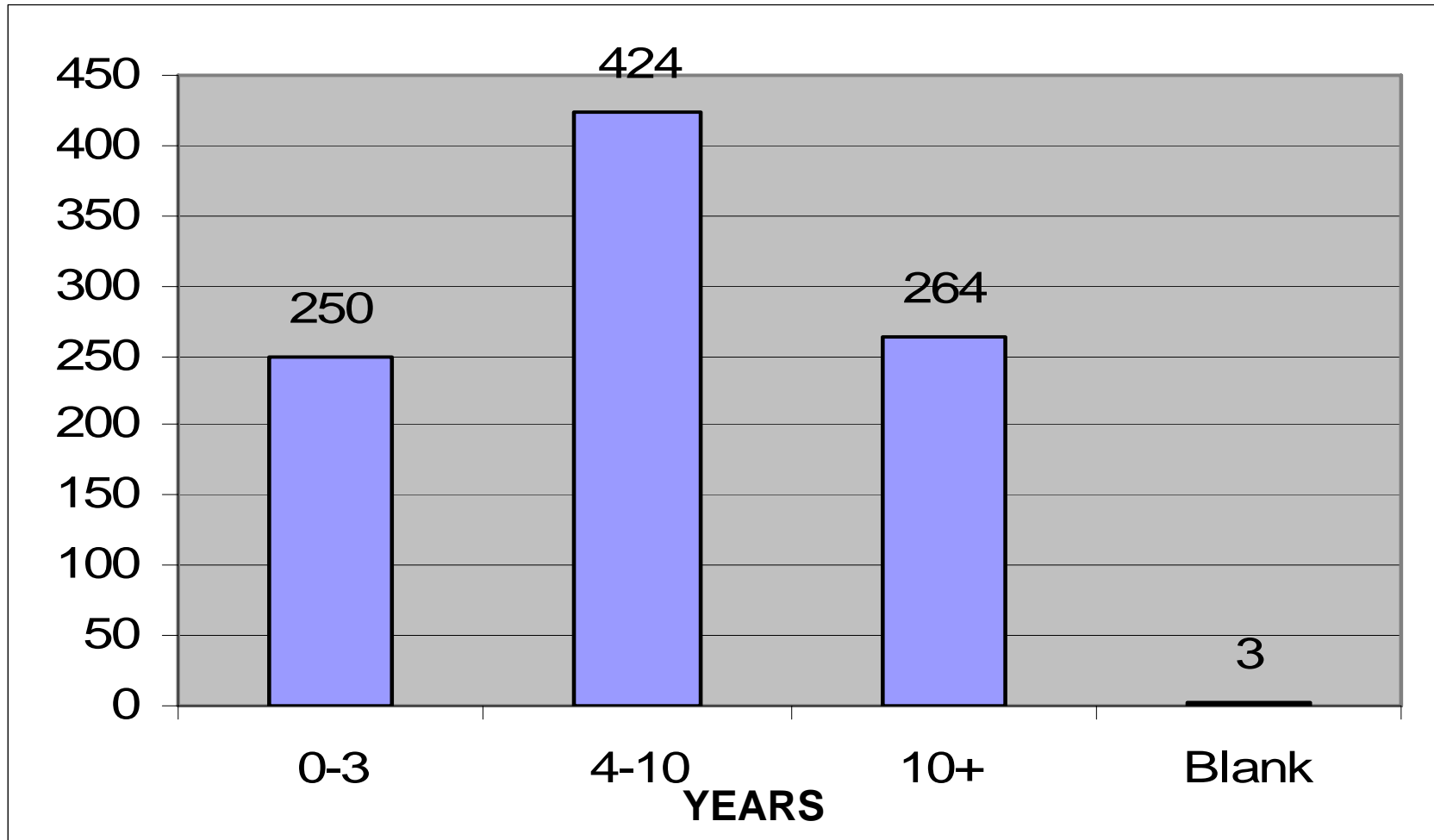
Survey responses



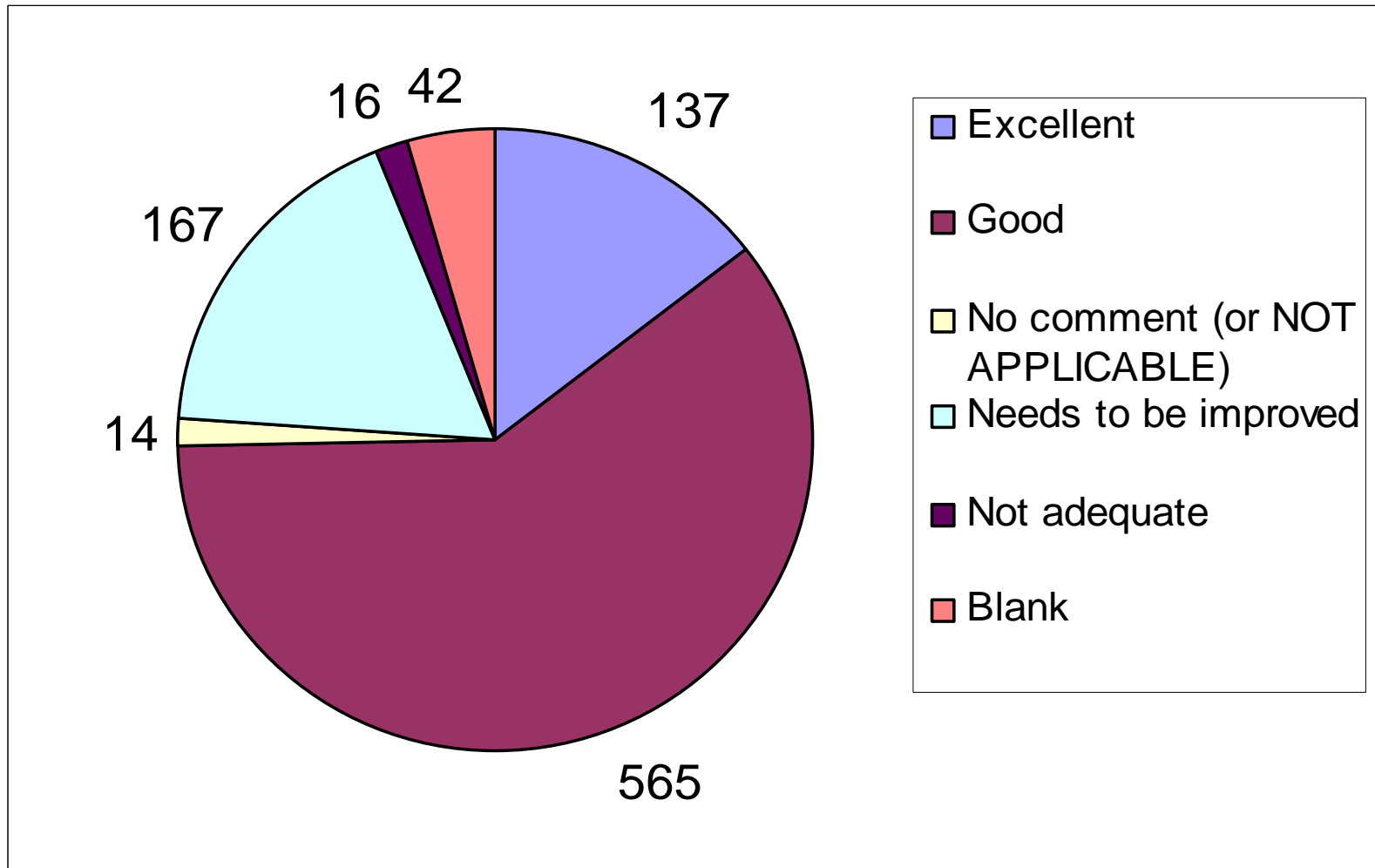
Size of organization



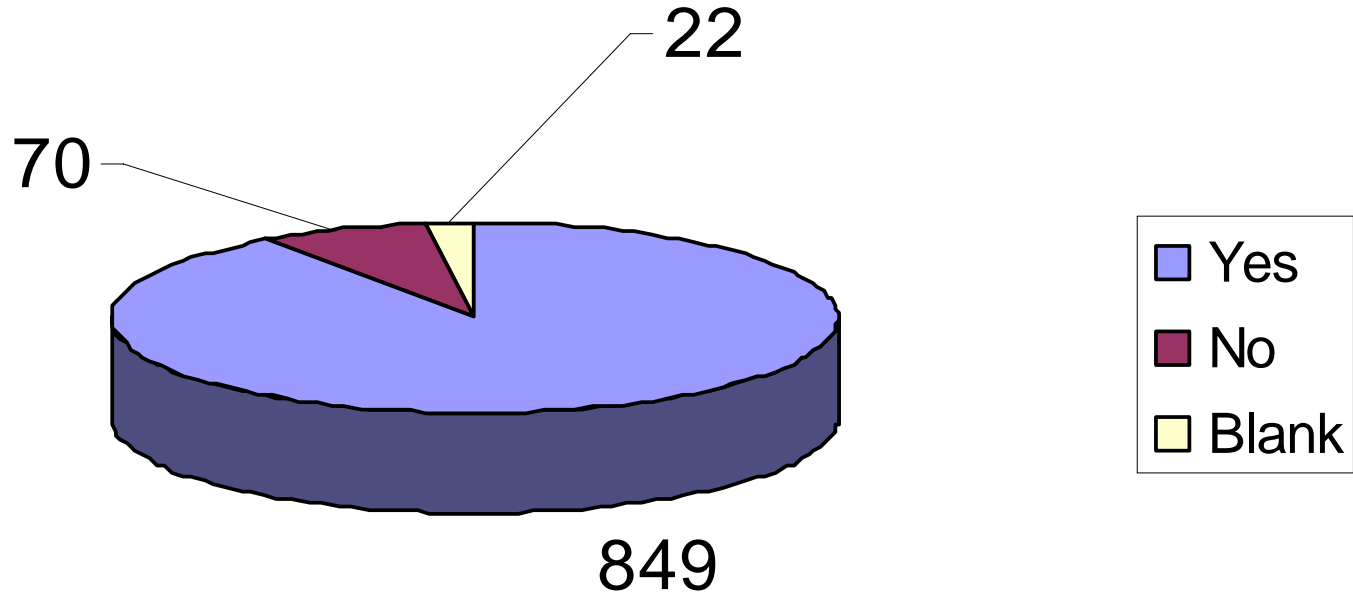
How long certified?



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

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

Maintaining the “Consistent Pair” of QMS standards



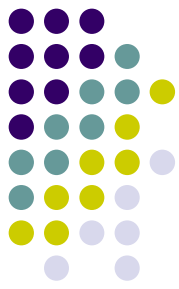
- The ‘consistency’ between the amendment of ISO 9001:2000 and the revision of ISO 9004:2000 means:
 - lack of conflict between the standards,
 - the standards fit well together, but are able to stand alone,
 - harmonized concepts and terminology,
 - easy transition from one standard to the other,
 - the two standards can be readily applied within the same quality management system.
 - each standard will have a structure that best meets the needs of its users

Compatibility with ISO 14001



- “Compatibility” means that common elements of the standards can be implemented by organizations in a shared manner, in whole or in part, without unnecessary duplication or the imposition of conflicting requirements.
- When maintaining compatibility with ISO 14001:2004 the following do not necessarily represent potential conflicts:
 - Different text in common elements or terminology
 - Different numbering of the clauses
 - Different models and structure
 - Inclusion of guidance, notes or annexes

Compatibility with Sector specific and other standards



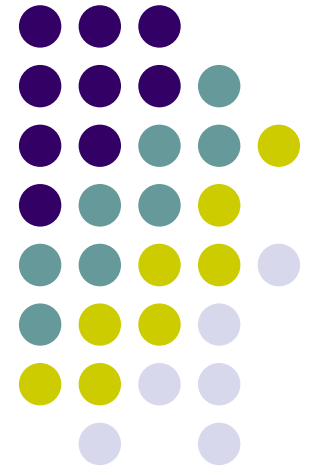
- Sector standards based on ISO 9001:2000
 - Example ISO/TS 16949; TL 9000
- Other management system standards that are based on ISO 9001:2000 and use its structure and text.

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.
- Concept of the “Consistent Pair” (ISO 9001 and 9004) to be maintained, but with more flexible criteria for “consistency”

Schedule (ISO 9001 and 9004)



- 2004 – User survey results received and analyzed; systematic review performed
- 2005 – Design specs approved
- 2006/2008 – Drafting and consensus process
- 2009 – Publication
- 2009/2010 – Transition period for ISO 9001 certification
 - To be defined by ISO and IAF (likely to be 18 months)



For further information:

- ISO web site www.iso.org
- Your National Standards Body
- ISO Liaison Member web sites
- ISO/TC176/SC2 website
- ISO Management Systems magazine
- ISO Press releases



- Was war Ihnen besonders wichtig?
- Welche weiteren Informationen benötigen Sie?
- Wie ist Ihre Meinung zu den dargestellten Ansätzen?



**Vielen Dank für
Ihre
Aufmerksamkeit**

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