



XVIII Foro
Mundial
de la Calidad y de la
Gestión para la Mejora
INLAC 2014

27 al 30 de Mayo • Cancún, México



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ISO 9001 history, At A Glance

–9001/9004 first published in 1987, undergone three revisions: 1994, 2000 and minor changes in 2008

YEAR	HISTORY
1987	Standard was based on traditional quality assurance standard used in Manufacturing sector
1994	Minor revision, without significant change
2000	Concept of eight quality management principles: Customer focus, leadership, involvement of people, process approach, system approach, fact-based decision making, continual improvement, mutually beneficial supplier relationships
2008	Minor revision, without significant change

ISO 9001 history, At A Glance.. Cont.



Why Change?

- To be more relevant to changing business needs
- To show continuous improvement and clear value to organization
- To make ISO 9001 the #1 Quality Management System

Justification
Study

WW
USER
Survey

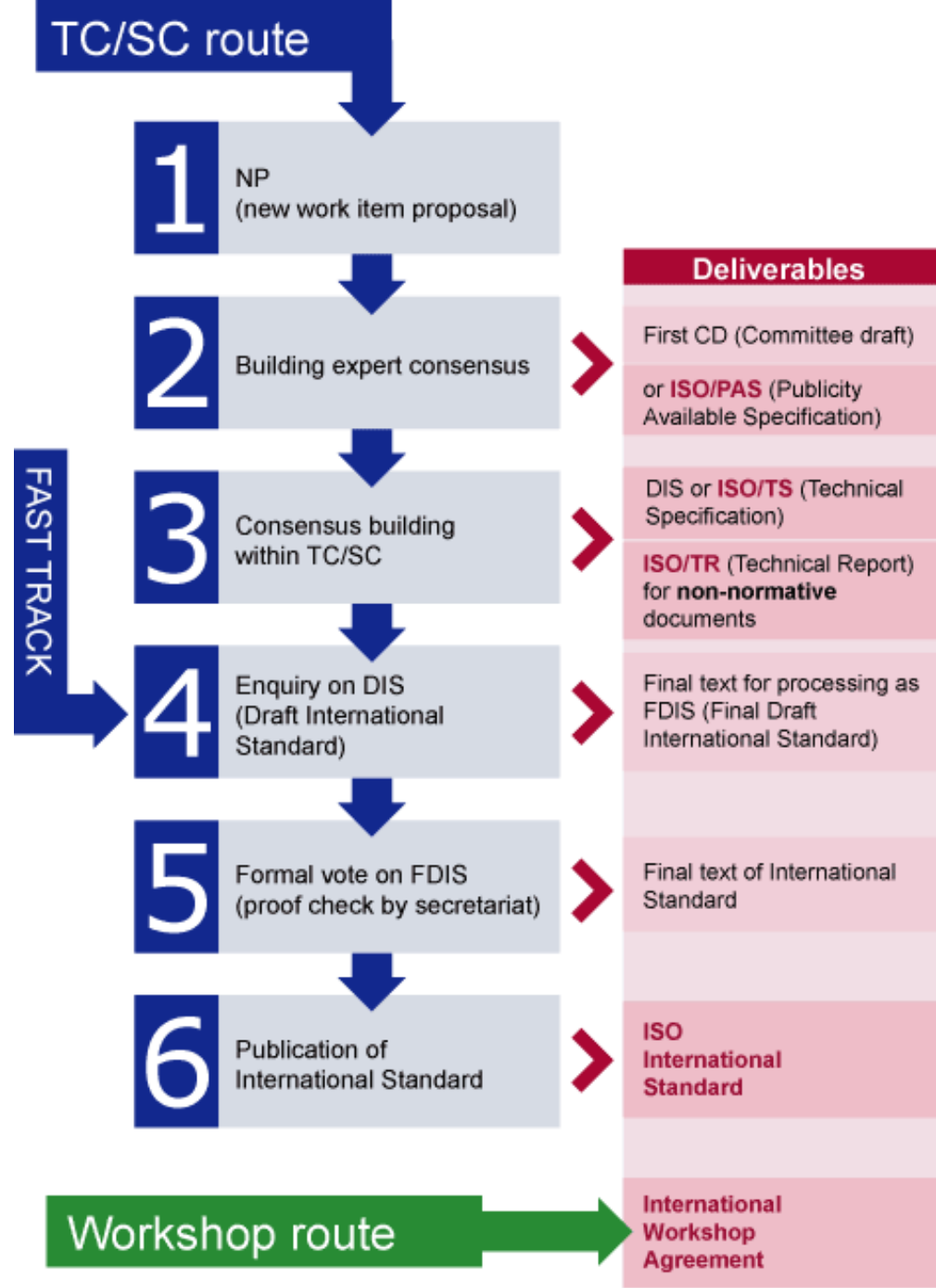
Future
Concepts
Work Group
(WG)

Quality
Management
Principles
(QMP)
WG

Innovation.....

- It is a golden age of technology and innovation. These two are transforming:
 - The way we do business
 - The way we work
 - The way we communicate
 - The way we live
 - The way we learn





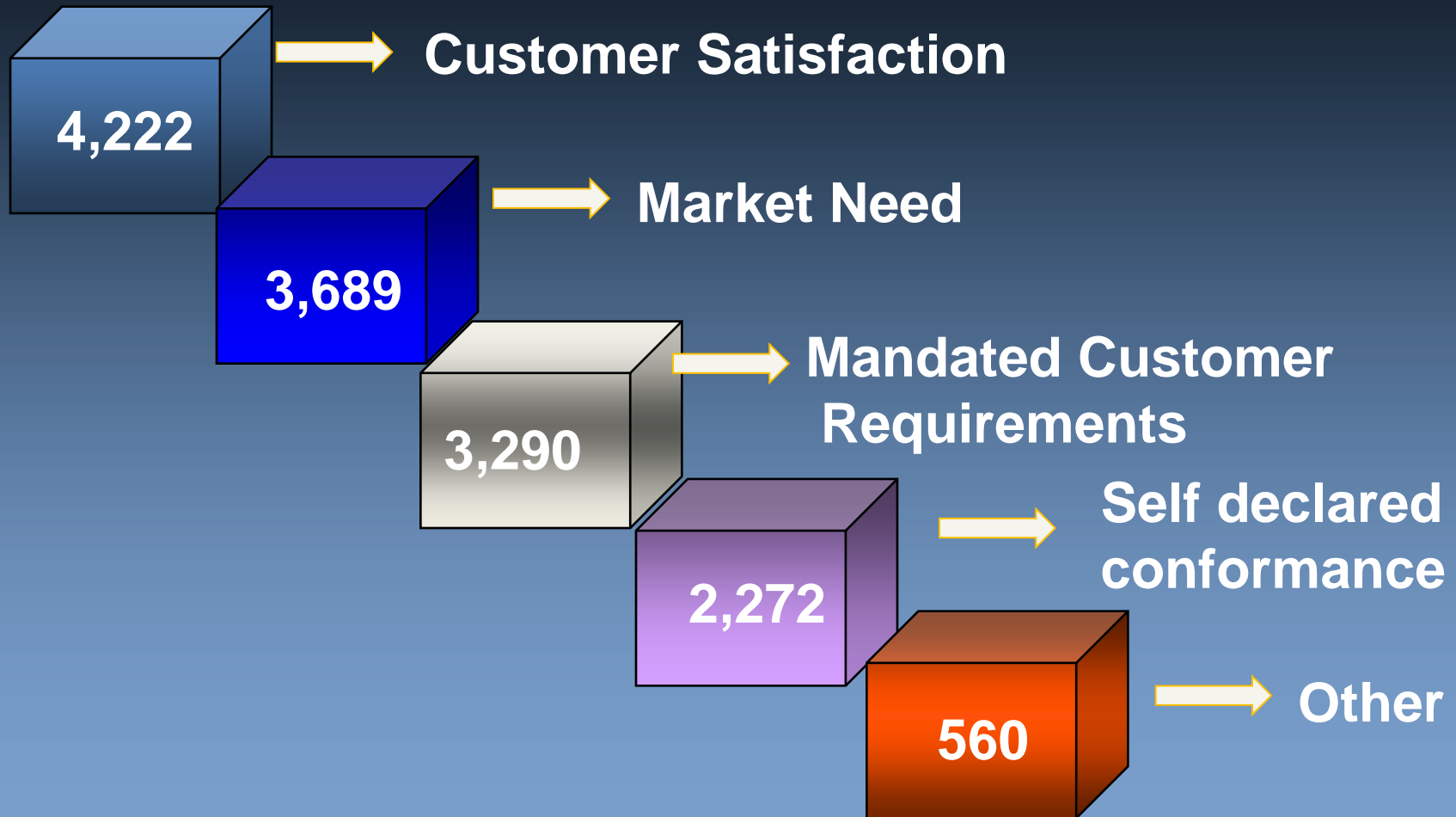
6/4/2014

Design Inputs

- **WW Survey**
- **Future Concepts**
- **Quality Management principles**
- **SC2 Mission & Vision**
- **Annex SL**
- **The needs of, and the impact on other interested parties were considered, liaisons etc.**
- **Comments received through the "systematic review", and on the "proposed actions" papers**
- **Number of other reference input documents such as ISO 9001:2008 Introduction & Support Package set of documents and Frequently Asked Questions; ISO 31000 Risk management etc.....**
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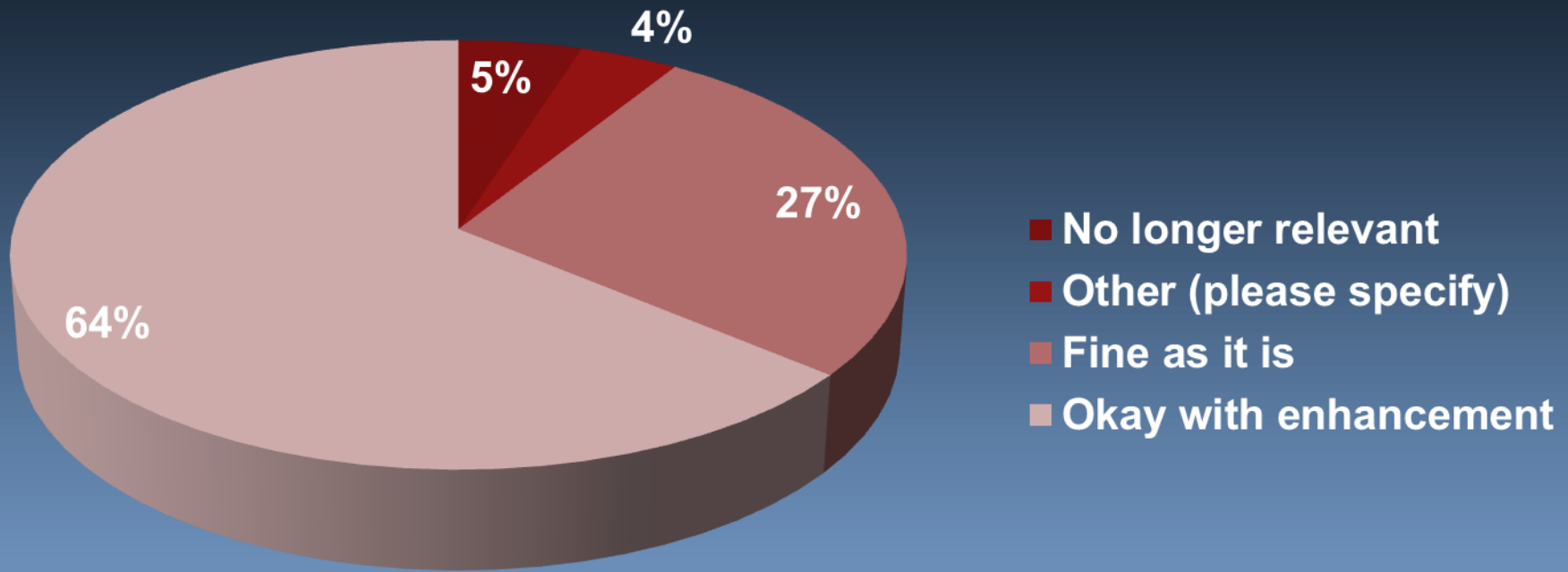
Recent World-wide 9001 Survey results

Influencing Factors for 9001 Certification (multiple choice)



Future Relevance of ISO 9001:2008

(9001 WW Survey Result)



Importance of New Concepts in ISO 9001

How important is it to incorporate the following concepts into ISO 9001?

Concept	% in Favor
Resource Management	75
Voice of Customer	74
Measures (performance, satisfaction, ROI)	72
Knowledge Management	72
Integration of Risk Mgmt.	73
Systematic problem solving & learning	73
Self-assessment tool	71
Strategic Planning	68
Innovation	65
Use of technology to develop/implement the reqs. Of the Standard	63
Life Cycle Management	62
Use of technology to run your business	61
Financial resources of the organization	55
Supporting Quality Tools (Six sigma Lean, SPC)	55

Key User Inputs from the World-wide Survey



- ISO, as it is, must change to be relevant
- Integrate with other MSS (EMS etc.)
- Provide one integral approach to the management of the organization for Leadership commitment & understanding, strategic planning, management buy-in
- Ensure **efficiency/effectiveness** of audits and address problems in certification audits
- Include tools and risk management

Weak Areas of Implementation of 9001

ISO 9001—Its relevance and impact in Asian Developing Economies: Project initiated by UNIDO, funded by Norad and supported with technical inputs by ISO and the IAF.

- **Emphasis on continual improvement**
- **Constant focus on preventive action**
- **Root cause analysis and weak preventive actions**
- **Use of process approach**
- **Handling of Customer Complaints**



**Guidance Documents?
White Papers?
VoDs?**



Quality Management Principles : Seven quality management principles on which the ISO portfolio of quality management system standards are based.

Customer Focus

a) **Statement**

- The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations.

b) **Rationale**

- Sustained success is achieved when an organization attracts and retains the confidence of customers and other interested parties on whom it depends. Every aspect of customer interaction provides an opportunity to create more value for the customer. Understanding current and future needs of customers and other interested parties contributes to sustained success of an organization.

Leadership

a) **Statement**

- Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the quality objectives of the organization.

b) **Rationale**

- Creation of unity of purpose, direction and engagement enable an organization to align its strategies, policies, processes and resources to achieve its objectives

Engagement Of People

a) **Statement**

- It is essential for the organization that all people are competent, empowered and engaged in delivering value.
- Competent, empowered and engaged people throughout the organization enhance its capability to create value.

b) **Rationale**

- To manage an organization effectively and efficiently, it is important to involve all people at all levels and to respect them as individuals. Recognition, empowerment and enhancement of skills and knowledge facilitate the engagement of people in achieving the objectives of the organization.

Process Approach

a) **Statement**

- **Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system.**

b) **Rationale**

- **The quality management system is composed of interrelated processes. Understanding how results are produced by this system, including all its processes, resources, controls and interactions, allows the organization to optimize its performance.**

Improvement

a) **Statement**

- **Successful organizations have an ongoing focus on improvement.**

b) **Rationale**

- **Improvement is essential for an organization to maintain current levels of performance, to react to changes in its internal and external conditions and to create new opportunities**

Evidence Based Decision Making

a) **Statement**

- **Decisions based on the analysis and evaluation of data and information are more likely to produce desired results.**

b) **Rationale**

- **Decision-making can be a complex process, and it always involves some uncertainty. It often involves multiple types and sources of inputs, as well as their interpretation, which can be subjective. It is important to understand cause and effect relationships and potential unintended consequences. Facts, evidence and data analysis lead to greater objectivity and confidence in decisions made.**

Relationship Management

a) **Statement**

- For sustained success, organizations manage their relationships with interested parties, such as suppliers.

b) **Rationale**

- Interested parties influence the performance of an organization. Sustained success is more likely to be achieved when an organization manages relationships with its interested parties to optimize their impact on its performance. Relationship management with its supplier and partner network is often of particular importance.

Disclaimer

- Although the information provided here today is meant to give an accurate picture of the revision to ISO 9001, any opinions expressed by the presenter are not necessarily official views of ISO/TC176 or of the Working Group responsible for developing these updates.

Disclaimer

- The information presented today is based on the Draft International Standard (DIS) of ISO 9001.
- The information presented in this presentation related to the revision of ISO 9001 is not final and should not be used for making changes to existing quality management systems.
- The contents of ISO 9001:2015 are subject to change and should not be used in any contractual or legally binding agreements.

ISO 9001:2015 DIS

- Understanding the “biggest changes” to the standard.
 - Structure and Terminology
 - Process Approach
 - Products and Services
 - Context of Organization
 - Documented Information
 - Externally provided products and services
 - Risk Based Thinking
 - 6.1 Planning
 - Applicability
 - Organization of Knowledge

ISO 9001:2015 DIS

- The keys to better understanding of many of the changes in the ISO 9001:2015 (DIS) revision are the Introduction and the Annex.

STRUCTURE

High level structure

- a new common format has been developed for use in all management system standards
 - *standardized core text and structure*
 - *standardized core definitions*

Organizations implementing multiple management systems (e.g. quality, environmental, information security) can achieve better integration and easier implementation

The high level structure and common text is public information and can be found in Annex SL of the www.iso.org/directives

Annex SL - Purpose

- Enhance the consistency and alignment of ISO management system standards by providing a unifying and agreed high level structure, identical core text and common terms and core definitions.

Annex SL – Who Benefits

- Organizations who implement multiple management system standards.
- Integrated
- Meet the requirements of two or more management system standard simultaneously.
 - ISO 9001
 - ISO 14001
 - ISO 20001

Annex SL and ISO 9001:2015

- The goal is to develop the new ISO 9001 using the new structure as foundation.
- If an issue arises that requires the request for a deviation, ISO TC 176/SC2 will be informed and a decision will be taken for any further action.

Annex SL Structure

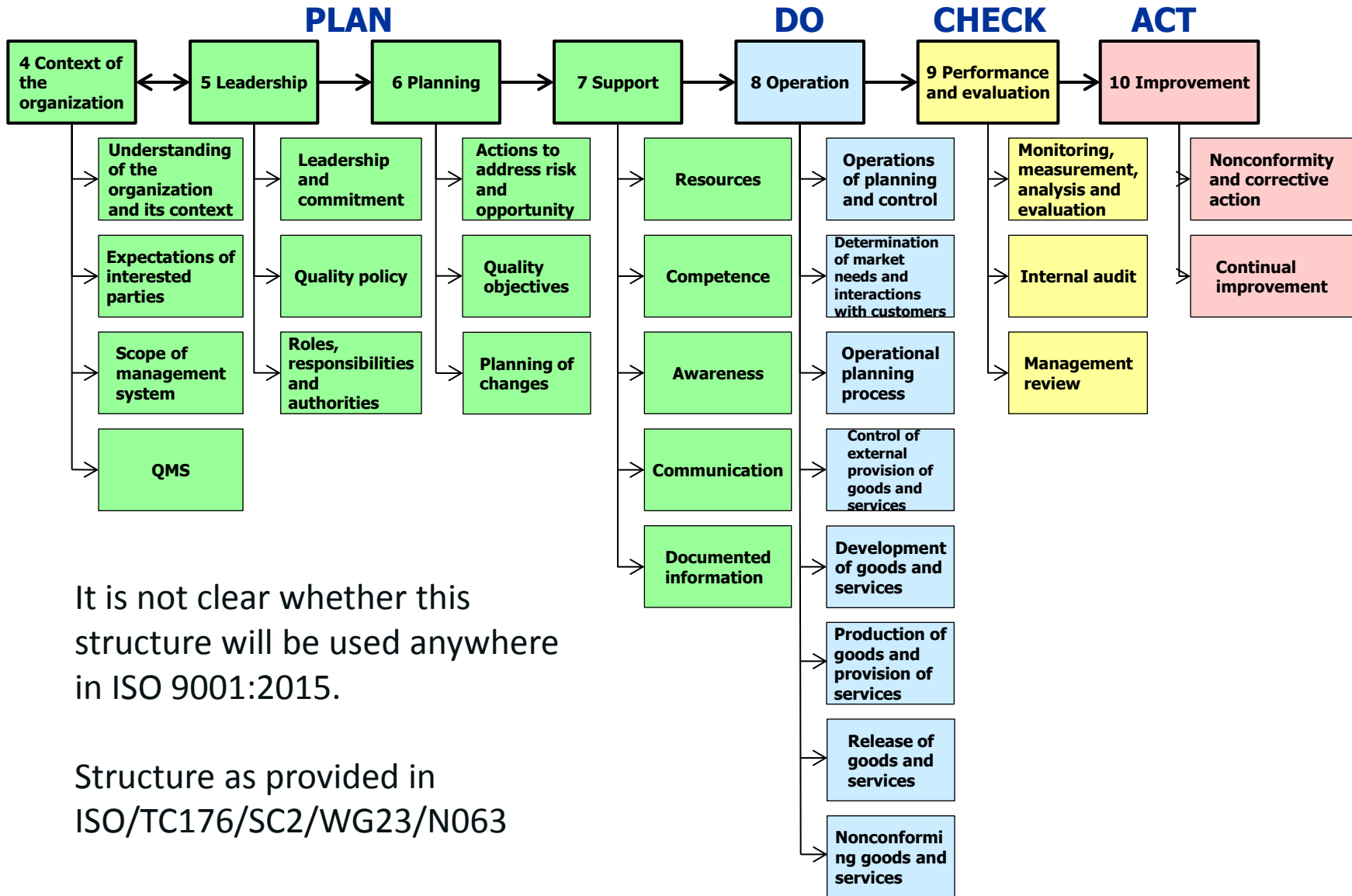
Annex SL

- 4 Context of Organization
- 5 Leadership Planning
- 6 Planning
- 7 Support
- 8 Operation
- 9 Performance & Evaluation
- 10 Improvement

ISO 9001:2008

- 4 Quality Management System
- 5 Management Responsibility
- 6 Resource Management
- 7 Product Realization
- 8 Measurement, Analysis, Improvement

QMS Structure



It is not clear whether this structure will be used anywhere in ISO 9001:2015.

Structure as provided in ISO/TC176/SC2/WG23/N063

ISO 9001:2015 DIS

Annex A.1 Structure and Terminology

- *The clause structure and some of the terminology of this International Standard, in comparison with ISO 9001:2008, have been changed to improve alignment with other management systems standards.*
- *The consequent changes in the structure and terminology do not need to be reflected in the documentation of an organization's quality management system.*
- *The structure of clauses is intended to provide a coherent presentation of requirements rather than a model for documenting an organization's policies, objectives and processes. There is no requirement for the structure of an organization's quality management system documentation to mirror that of this International Standard.*

ISO 9001:2015 DIS

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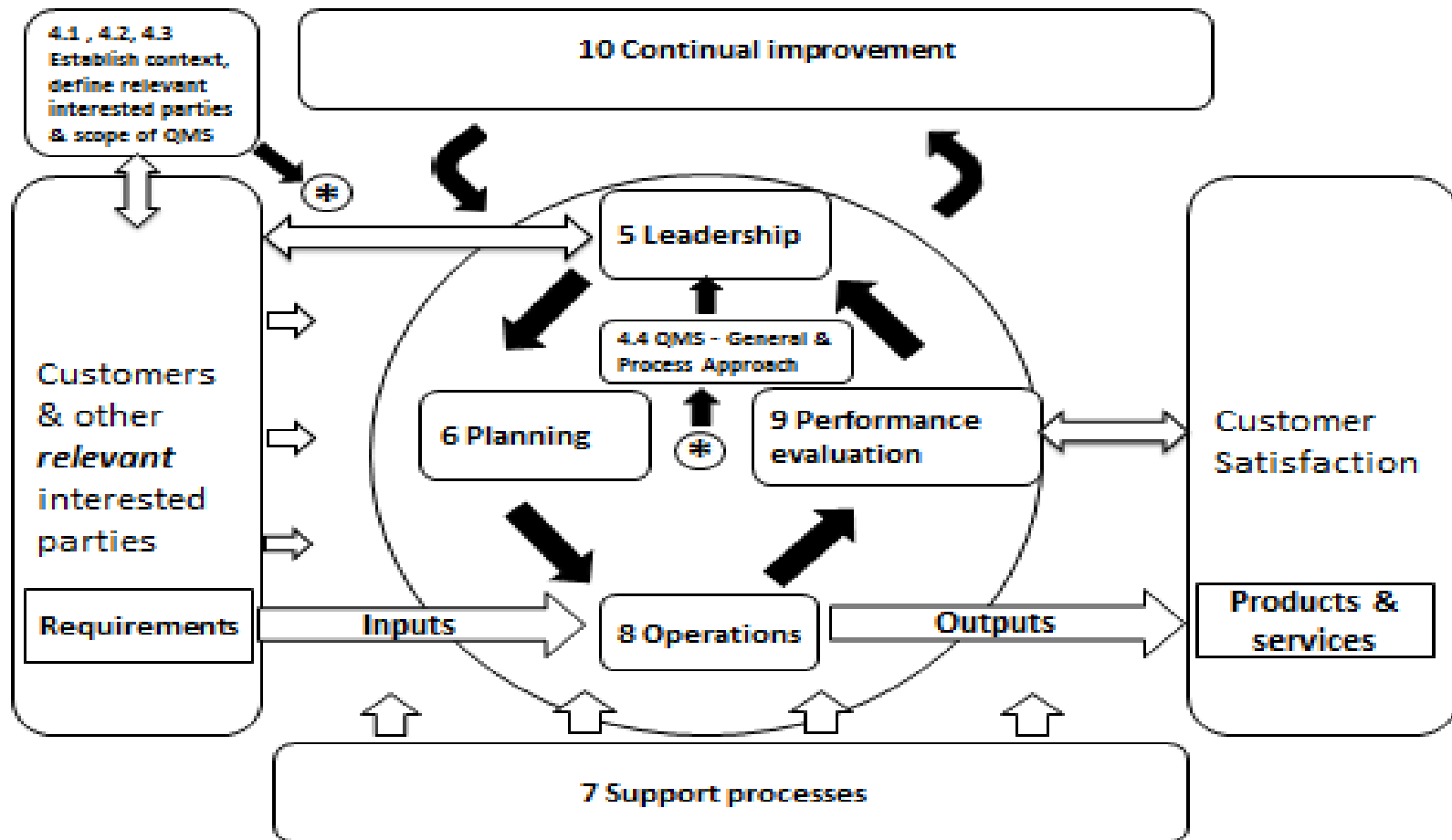
PROCESS APPROACH

Process Approach

- Clause 4.4 includes requirements for process approach. Some requirements are more prescriptive.
 - *the inputs required and the outputs expected from these processes;*
 - *the resources needed and ensure their availability;*
 - *the assignment of the responsibilities and authorities for these processes;*
 - *the risks and opportunities in accordance with the requirements of 6.1, and plan and implement the appropriate actions to address them;*
 - *the methods for monitoring, measuring, as appropriate, and evaluation of processes and, if needed, the changes to processes to ensure that they achieve intended results; and*



Process Approach is Still Applicable



ISO 9001:2015 DIS

0.3 Process approach

- *The process approach applies systematic definition and management of processes and their interactions so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using a “Plan-Do-Check-Act” (PDCA) methodology (see 0.4) with an overall focus on “Risk-based thinking” aimed at preventing undesirable outcomes (see 0.5).*

PRODUCTS AND SERVICES

ISO 9001:2015 **Proposed**

More easily applied to service industries

- ISO 9001:2008 used product to include products, services, processed materials, and hardware.
- Feedback indicated that the service industry continued to have difficulty with the application of ISO 9001.
- Not using the word service further complicated the standard for these users.
- The word “product” has been replaced by “products and services” when referring to deliverables to the customer.

ISO 9001:2015 DIS

A.2 Products and services

- *The specific inclusion of “services” is intended to highlight the differences between products and services in the application of some requirements.*
- *In most cases, the terms “products” and “services” are used together. Most outputs that organizations provide to customers, or are supplied to them by external providers, include both products and services. The organization needs to take into account where, for example, a tangible product has some associated intangible service or an intangible service has some associated tangible product.*

CONTEXT OF THE ORGANIZATION

Context of the Organization

- Clauses 4.1 Understanding the organization and its context and 4.2 Understanding the needs and expectations of interested parties. require the organization to determine the issues and requirements that can impact the planning of the quality management system.

ISO 9001:2015 DIS

A.3 Context of the organization

- Interested parties cannot go beyond the scope of ISO 9001.
- There is no requirement to go beyond interested parties that are relevant to the quality management system. *Determining what is relevant or not relevant is dependent on whether or not it has an impact on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements or the organization's aim to enhance customer satisfaction.*
- *The organization can decide to determine additional needs and expectations that will assist it to meet its quality objectives. However, it is at the organization's discretion whether or not to accept additional requirements to satisfy interested parties beyond what is required by this International Standard.*

RISK-BASED THINKING

The main objectives of ISO 9001

- to provide confidence in the organization's ability to consistently provide customers with conforming goods and services
- To enhance customer satisfaction

The concept of “risk” in the context of ISO 9001 relates to the uncertainty in achieving these objectives

What is “risk-based thinking”?

- risk-based thinking is something we all do automatically and often sub-consciously
- The concept of risk has always been implicit in ISO 9001 – this revision makes it more explicit and builds it into the whole management system
- risk-based thinking is already part of the process approach
- risk-based thinking makes preventive action part of the routine
- risk is often thought of only in the negative sense. Risk-based thinking can also help to identify opportunities. This can be considered to be the positive side of risk

Where is risk addressed in
the current draft of
ISO 9001:2015?

Risk in the clauses - Process Approach, Leadership, Planning

- in Clause 4 the organization is required to determine the risks which can affect its ability to meet these objectives
- in Clause 5 top management are required to commit to ensuring Clause 4 is followed
- in Clause 6 the organization is required to take action to address risks and opportunities

Risk in Clauses – Operation, Evaluation, Improvement

- Clause 8 - the organization is required to have processes which identify and address risk in its operations
- Clause 9 the organization is required to monitor, measure, analyse and evaluate the risks and opportunities
- In Clause 10 the organization is required to improve by responding to changes in risk

ISO 9001:2015 DIS

0.5 “Risk-based thinking”

- *This International Standard makes risk-based thinking more explicit and incorporates it in requirements for the establishment, implementation, maintenance and continual improvement of the quality management system.*
- *Organizations can choose to develop a more extensive risk-based approach than is required by this International Standard, and ISO 31000 provides guidelines on formal risk management which can be appropriate in certain organizational contexts.*

ISO 9001:2015 DIS

A.4 Risk-based approach

- *This International Standard requires the organization to understand its context (see clause 4.1) and determine the risks and opportunities that need to be addressed (see clause 6.1).*
- *One of the key purposes of a quality management system is to act as a preventive tool. Consequently, this International Standard does not have a separate clause or sub-clause titled 'Preventive action'. The concept of preventive action is expressed through a risk-based approach to formulating quality management system requirements.*

APPLICABILITY

ISO 9001:2015 DIS

- ISO 9001:2015 does not address exclusions, but applicability.

ISO 9001:2015 DIS

A.5 Applicability

- The application of requirements may vary.
- *Where a requirement can be applied within the scope of its quality management system, the organization cannot decide that it is not applicable. Where a requirement cannot be applied (for example where the relevant process is not carried out) the organization can determine that the requirement is not applicable. However, this non-applicability cannot be allowed to result in failure to achieve conformity of products and services or to meet the organization's aim to enhance customer satisfaction.*

DOCUMENTED INFORMATION

ISO 9001:2015 DIS

- Documented information replaces the following terms:
 - Documented procedure
 - Document
 - Record

ISO 9001:2015 DIS

A.6 Documented information

- *Where ISO 9001:2008 would have referred to documented procedures (e.g. to define, control or support a process) this is now expressed as a requirement to **maintain** documented information.*
- *Where ISO 9001:2008 would have referred to records this is now expressed as a requirement to **retain** documented information.*

ORGANIZATIONAL KNOWLEDGE

ISO 9001:2015 DIS

- Clause **7.1.6 Organisational knowledge** addresses the need to determine and maintain the knowledge obtained by the organization, including by its personnel, to ensure that it can achieve conformity of products and services.
- The organization shall consider this knowledge when making changes in the organization.

ISO 9001:2015 DIS

A.7 Organisational knowledge

- *The process for considering and controlling past, existing and additional knowledge needs to take account of the organization's context, including its size and complexity, the risks and opportunities it needs to address, and the need for accessibility of knowledge. The balance between knowledge held by competent people and knowledge made available by other means is at the discretion of the organization, provided that conformity of products and services can be achieved.*

EXTERNALLY PROVIDED PRODUCTS AND SERVICES

ISO 9001:2015 DIS

- Purchased products has been replaced with externally provided products and services.

ISO 9001:2015 DIS

A.8 Control of externally provided products and services

- *Clause 8.4 Control of externally provided products and services addresses all forms of external provision, whether it is by purchasing from a supplier, through an arrangement with an associate company, through the outsourcing of processes and functions of the organization or by any other means.*

Transition from ISO 9001:2008

Proceed with Caution



Transition

- There will be a three-year transition time after the publication of ISO 9001:2015.
 - Estimated September 2015 – September 2018
 - Details for how this transition will work will be available from the International Accreditation Forum and specific certification bodies.
- Organizations can start integrating change with the understanding that the revision is not complete and additional changes may be required.
 - Proceed with caution.



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4 Context of the Organization

ISO 9001:2015	ISO 9001:2008
4.1 Understanding the organization and its context	4.1 General Introduction
4.2 Understanding the needs and expectations of interested parties	4.1 General
4.3 Determining the scope of the quality management system	1.2 Application 4.2.2 Quality Manual
4.4 Quality management system and its processes	4.1 General

This is not the official cross reference to be published with ISO 9001:2015.



5 Leadership

ISO 9001:2015	ISO 9001:2008
5.1 Leadership and commitment 5.1.1 Leadership and commitment for the quality management system	5.1 Management Commitment
5.1.2 Customer focus	5.2 Customer Focus
5.2 Quality policy	5.3 Quality Policy
5.3 Organizational roles, responsibilities and authorities	5.5.1 Responsibility and Authority 5.5.2 Management Representative

This is not the official cross reference to be published with ISO 9001:2015.



Structure - 6 Planning for the quality management system

ISO 9001:2015	ISO 9001:2008
6.1 Actions to address risks and opportunities	5.4.2 Quality Management System Planning 8.5.3 Preventive Action
6.2 Quality objectives and planning to achieve them	5.4.1 Quality Objectives
6.3 Planning of changes	5.4.2 Quality Management System Planning

This is not the official cross reference to be published with ISO 9001:2015.



Structure – 7 Support

ISO 9001:2015	ISO 9001:2008
7.1 Resources and People 7.1.1 General 7.1.2 People	6.1 Provision of Resources
7.1.3 Infrastructure	6.3 Infrastructure
7.1.4 Environment for the operation of processes	6.4 Work Environment
7.1.5 Monitoring and measuring resources	7.6 Control of monitoring and Measuring Equipment
7.1.6 Organizational knowledge	New
7.2 Competence	6.2.1 General 6.2.2 Competence, Training and Awareness
7.3 Awareness	6.2.2 Competence, Training and Awareness



Structure – 7 Support

ISO 9001:2015	ISO 9001:2008
7.4 Communication	5.5.3 Internal Communication
7.5 Documented information 7.5.1 General 7.5.2 Creating and updating 7.5.3 Control of documented Information	4.2.1 General 4.2.3 Control of Documents 4.2.4 Control of Records

This is not the official cross reference to be published with ISO 9001:2015.



Structure - 8 Operations

ISO 9001:2015	ISO 9001:2008
8.1 Operational planning and control	7.1 Planning of Product Realization
8.2 Determination of requirements for products and services	7.2.1 Determination of requirements related to the product
8.2.1 Customer communication	7.2.3 Customer Communication
8.2.2 Review of requirements related to the products and services	7.2.2 Review of requirements related to the product
8.2.3 Review of customer requirements	7.2.2 Review of requirements related to the product

This is not the official cross reference to be published with ISO 9001:2015.



Structure - 8 Operations (Cont.)

ISO 9001:2015	ISO 9001:2008
8.3 Design and development of products and services	
8.3.1 General	
8.3.2 Design and development planning	7.3.1 Design and Development Planning
8.3.3 Design and development Inputs	7.3.2 Design and Development Inputs
8.3.4 Design and development controls	7.3.4 Design and Development Review 7.3.5 Design and Development Verification 7.3.6 Design and Development Validation
8.3.5 Design and development outputs	7.3.3 Design and Development Outputs
8.3.6 Design and development changes	7.3.7 Design and Development Changes



Structure - 8 Operations (Cont.)

ISO 9001:2015	ISO 9001:2008
8.4 Control of externally provided products and services 8.4.1 General	7.4.1 Purchasing Process
8.4.2 Type and extent of control of external provision	7.4.1 Purchasing Process
8.4.3 Information for external providers	7.4.2 Purchasing Information
8.5 Production and service provision 8.5.1 Control of production and service provision	7.5.1 Control of Production and Service Provision
8.5.2 Identification and traceability	7.5.3 Identification and Traceability
8.5.3 Property belonging to customers or external providers	7.5.4 Customer Property
8.5.4 Preservation	7.5.5 Preservation of Product
8.5.5 Post-delivery activities	7.5.1 Control of Production and Service Provision



Structure - 8 Operations (Cont.)

ISO 9001:2015	ISO 9001:2008
8.5.6 Control of changes	New
8.6 Release of products and services	7.4.3 Verification of Purchased Product
8.7 Control of nonconforming process outputs, products and services	8.3 Control of Nonconforming Product



Structure - 9 Performance Evaluation

ISO 9001:2015	ISO 9001:2008
9.1 Monitoring, measurement, analysis and evaluation	8.1 General
9.1.1 General	8.1 General
9.1.2 Customer satisfaction	8.2.1 Customer Satisfaction
9.1.3 Analysis and evaluation	8.4 Analysis of Data
9.2 Internal audit	8.2.2 Internal Audit
9.3 Management review	5.6 Management Review

This is not the official cross reference to be published with ISO 9001:2015.



10 Improvement

ISO 9001:2015	ISO 9001:2008
10.1 General	8.5.1 Continual Improvement
10.2 Nonconformity and corrective action	8.5.2 Corrective Action
10.3 Continual Improvement	8.5.1 Continual Improvement



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¡GRACIAS!



4.1 Context of the organization

- The organization shall determine external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended outcome(s) of its XXX management system.



4.2 Understanding the needs and expectations of interested parties

- The organization shall determine:
 - — the interested parties that are relevant to the XXX management system;
 - — the relevant requirements of these interested parties.

- LMH NOTE: Interested parties are those that have an impact on the organization providing products and services that meet requirements.

-



4.3 Determining the scope of the XXX management system

- The organization shall determine the boundaries and applicability of the XXX management system to establish its scope.
- When determining this scope, the organization shall consider:
 - — the external and internal issues referred to in 4.1;
 - — the requirements referred to in 4.2.
- The scope shall be available as documented information.



- The exercise is based on Annex SL. There are quality management system specific requirements that are included in the Draft International Standard which will not be available for this breakout.
- Develop statements of guidance for each clause.
 - 4.1, 4.2, 4.3



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- Develop statements of guidance for each clause.
 - 4.1, 4.2, 4.3



6.1 Actions to address risks and opportunities

- When planning for the XXX management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:
 - — give assurance that the XXX management system can achieve its intended outcome(s);
 - — prevent, or reduce, undesired effects;
 - — achieve continual improvement.
- The organization shall plan:
 - a) actions to address these risks and opportunities;
 - b) how to:
 - — integrate and implement the actions into its XXX management system processes;
 - — evaluate the effectiveness of these actions.



6.2 XXX objectives and planning to achieve them

- The organization shall establish XXX objectives at relevant functions and levels.
- The XXX objectives shall:
 - a) be consistent with the XXX policy;
 - b) be measurable (if practicable);
 - c) take into account applicable requirements;
 - d) be monitored;
 - e) be communicated;
 - f) be updated as appropriate.
- The organization shall retain documented information on the XXX objectives.
- When planning how to achieve its XXX objectives, the organization shall determine:
 - — what will be done;
 - — what resources will be required;
 - — who will be responsible;
 - — when it will be completed;
 - — how the results will be evaluated.