

Brief presentation of:

- ISO High Level Structure for Management system standards
- Key changes in ISO 9001:2015 and ISO 14001:2015
- Transition period
- How to prepare for implementation of the new standards?

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Global Unit – Technology & Services

High Level Structure – in brief

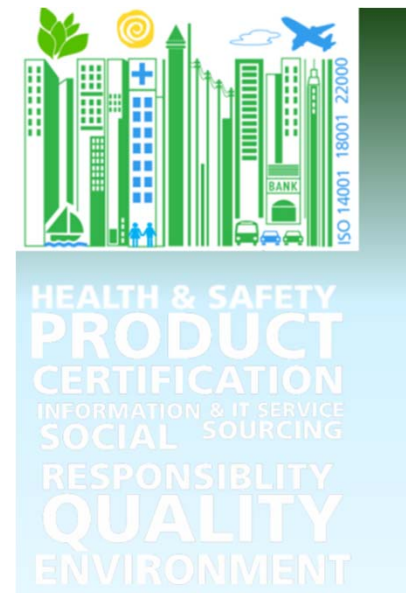
ISO decided in 2012 that all Management System standards shall use a common framework containing:

- Unified High Level Structure (HLS)
- Common Text and Terminology

Individual management systems standard will add additional “discipline-specific” requirements as required

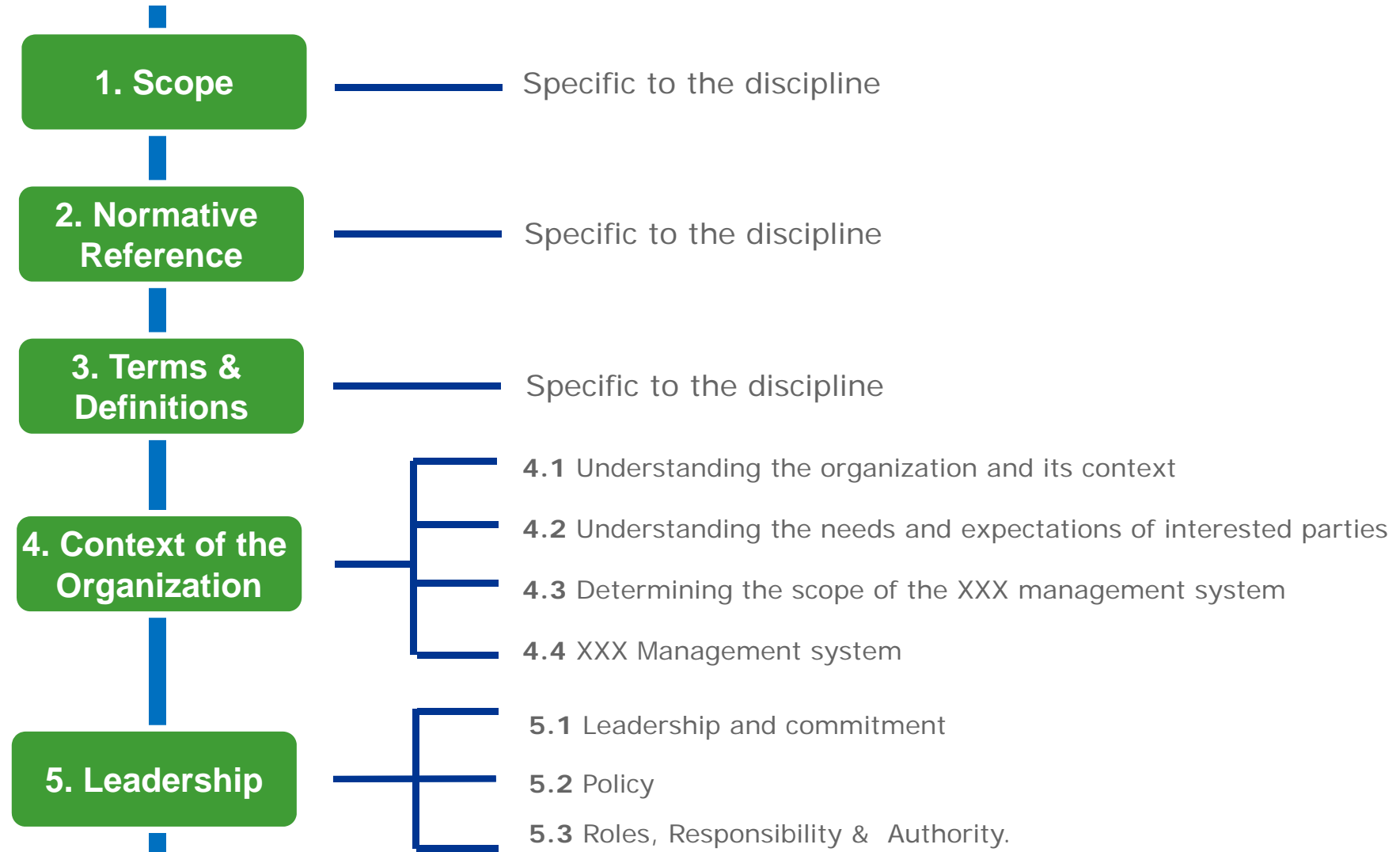
Main advantages:

- Enhanced compatibility of standards
- Easier to implement new standards
- Easier to integrate standards into a management system
- Increase value for users
- Increased effectiveness in standard development for the technical committees

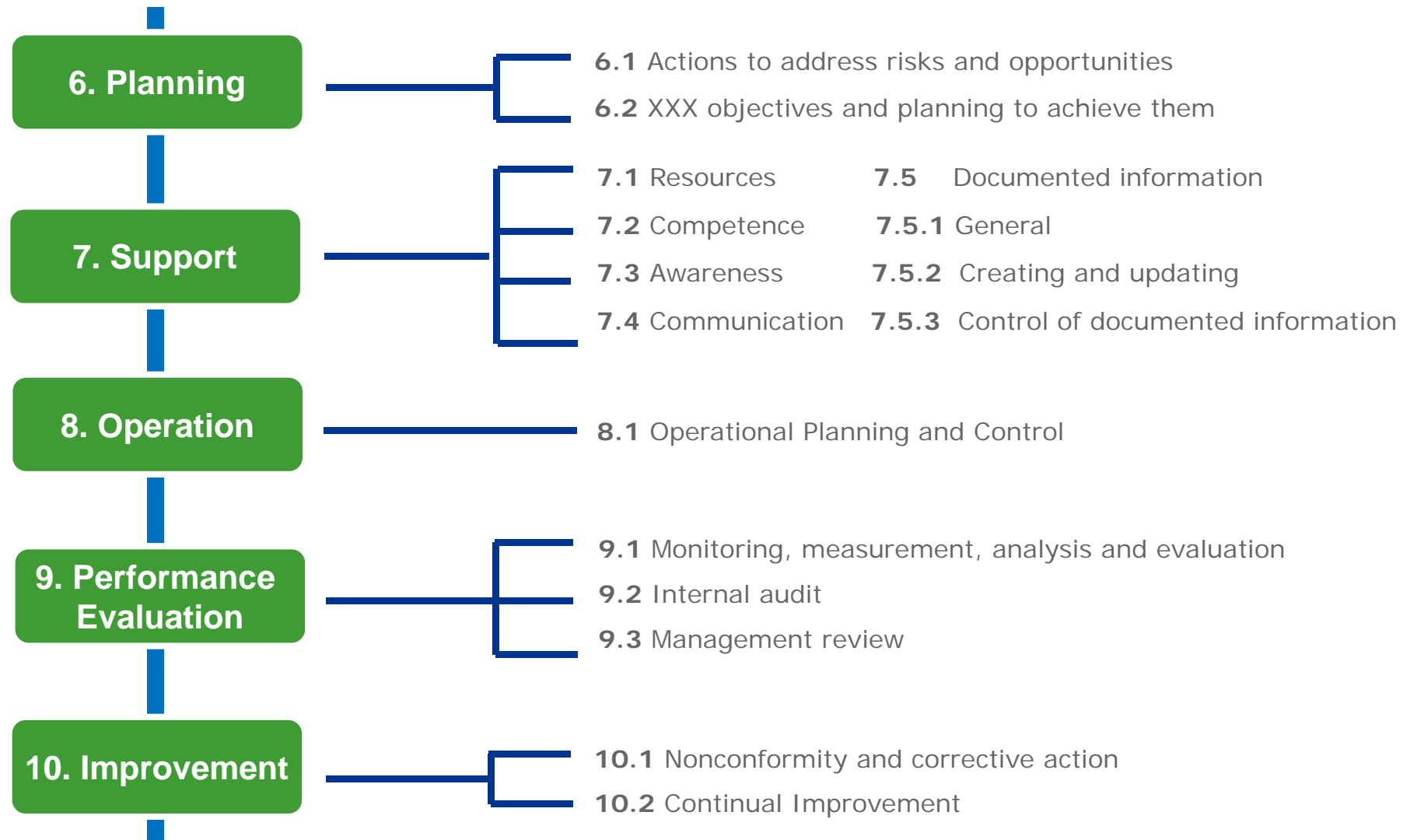


ISO 9001, ISO 14001 and the upcoming ISO 45001 are all using the common framework

HLS - 10 Clause structure



HLS – 10 Clause structure



What are the key changes?

- The changes incorporated into the 2015-editions compared to current editions of ISO 9001 and ISO 14001 can essentially be divided into:
 1. Changes due to the adoption of HLS which are therefore valid for both ISO 9001 and ISO 14001 (see slides 6-8); and
 2. Those other changes that are specific to ISO 9001:2008 (see slides 9-10) and ISO 14001:2004 (see slides 11-13) respectively.

Key changes induced by the HLS (ISO 9001 and ISO 14001)

- As a result of the HLS the structure and clauses of the standards are largely changed. Even when requirements are essentially unchanged between the editions, these are frequently found under a new clause/sub-clause.
- New clauses for **understanding of the context** of the organization to identify and understand factors that affect or can affect the ability to reach the intended results of its management system, including:
 - determination and monitoring of the external and internal influencing factors (ref. 4.1)
 - determination and monitoring of relevant interested parties and their needs and expectations (ref. 4.2)
- **Risks and opportunity management** (Ref. 6.1) to determine, consider and, where necessary, take action to address any risks or opportunities that may impact (either positively or negatively) the ability of MS to deliver its intended results or that could impact customer satisfaction.

Key changes induced by HLS (valid for both ISO 9001/ISO 14001)

- **Strengthened emphasis on “Leadership” and management commitment, including** to actively engage and take accountability for the effectiveness of the management system. (Ref. 5.1)
- Strengthened focus on objectives as drivers for improvements (6.2) & to measure, monitor, analyse and evaluate performance (9.1)
- More emphasis on control of planned changes and review of consequences of unintended changes (8.1)
- Extended requirements related to Communications (7.4): Includes also external communication and more prescriptive in respect of the “mechanics” of communication, including determination of what, when and how to communicate (see also specific 14001-related changes)
- No requirement for Quality/Environmental Manual, and the mandatory documented procedures (in ISO 9001:2008) no longer explicitly required.
However still required to have documented information



Note also the following related to HLS (ISO 9001 and ISO 14001)

- The HLS does not include a specific clause for or refer to the term “Preventive action”. However the concept of preventive action is considered to be implicitly embedded in the standards (e.g. through 6.1)
- “Documented information” is now the term used as replacement of ‘Documents’ and ‘Records’
- The term “Management representative” is no longer used, however the responsibilities of role still explicitly addressed
- Both standards address that they fit with the Plan-Do-Check-Act (PDCA) model

In addition there are some other key changes specific to each standard (see next slides)

Other ISO 9001 specific key changes (Compared with 2008-edition)

- “Risk based thinking” as basis for the management system is embedded throughout standard
- Process approach is still an important concept – with extended explicit requirements (Ref. 4.4)
- More detailed attention to the control of externally provided processes, products and services (requirements do not distinguish between purchasing and outsourced process, all is dependent on risks and required control) (Ref. 8.4)
- More focus on determination of extent of post-delivery activities (also based on product risks etc.) (Ref. 8.5.5)
- Extended requirements related to planning of needed changes to the management system (Ref. 6.3)
- Extended requirements for review and control of changes essential for production or service provision to ensure conformity with specified requirements (Ref. 8.5.6)
- Included new clause “Organizational knowledge” (Ref. 7.1.6) covering a more “strategic” consideration of knowledge needs

.....continues.....



Other ISO 9001 specific changes, continued (Compared with 2008-edition)

- Regarding scope and exclusions (Ref. 4.3) : All requirements within the scope shall be applied, if they can be applied. If not applicable, this needs to be justified as part of scope (i.e. not limited to clause 7 as in current edition). In conclusion the standard opens for exclusions, but these are clearly conditional.
- ISO 9000:2015 is indispensable for the use of ISO 9001:2015.
- ISO 9001:2015 has two informative annexes:
 - Annex A provides clarification on the new structure, terminology and concepts;
 - Annex B provides a list of QMS related standards developed by ISO TC 176, including standards in the 9000-series and 10000-series. These are designed to provide assistance to organisations seeking to establish or improve their quality management performance
- A new guideline ISO/TS 9002 “Quality management systems – Guideline for the application of ISO 9001” is under development. Timeline for release is not yet confirmed.



Other ISO 14001 specific key changes (Compared with 2004-edition)

- In general most of the key changes for 14001 are induced through the HLS (see previous slides). Those listed below are additional.



- **Broader environmental view**, including:

- **More emphasis on Life Cycle thinking**, examples:

- 1) Consideration of the life cycle perspective when determining the environmental aspects of activities, products and services (6.1.2). The life-cycle includes acquisition of raw materials, design, production, transportation/delivery, use, end-of-life treatment and final disposal.
(Note: This does not imply a requirement to do a formal life cycle assessment (LCA)).
 - 2) Determination of environmental requirements for the procurement of products and services (8.1 b))
 - 3) Establishing controls to ensure environmental requirements are addressed in the design and development process of its products/services considering each stage of the life cycle (8.1 a))
- Focus on protection of environment and not solely prevention of pollution (5.2)

ISO 14001 specific key changes, continued.... (Compared with 2004-edition)

- More specific requirements related to Performance evaluation (9.1.1), including:
 - What, when and how to monitor and measure (related to e.g. significant aspects, compliance obligations, operational controls)
 - Determination of criteria against which environmental performance is evaluated, and appropriate indicators
 - When the results from monitoring and measurements shall be analyzed and evaluated
 - Need for documented information (evidence of monitoring, measurements, analysis and evaluation results)

- Communication (7.4.1-7.4.3):
 - Communicated information shall be consistent with information generated within the EMS and shall be reliable (7.4.1) (i.e. quality and consistency of information)
 - Facilitation of feedback for improvement from employees or externals 7.4.2 b)



ISO 14001 specific key changes, continued.... (Compared with 2004-edition)

- The intended outcome of an EMS is improved environmental performance and not limited to improvement of the management system (Refer e.g. clause 1 and 4.4)
- Regarding Emergency preparedness and response (8.2):
 - Identification of potential emergency situations is now explicit in 6.1.1 (risks and opportunities)
 - Required to have process for how to prepare and respond to emergency situations. Actions shall be planned to prevent/mitigate impacts from emergency situations.
 - Relevant info regarding emergency preparedness and response shall be given to relevant interested parties
 - Documented information is required to be maintained to give confidence that processes are carried out as planned
- Note that Annex A still contains useful guidance for use of the standard (as in the current edition)

Transition timeline

- Publication date for the standards is 15.09.2015
- The transition time is 3 years from publication date. All certificates shall be transitioned within 15.09.2018. From this date the “old” standards cease to be valid.
- Current certificates can be transitioned at any planned audit in the transition period

- The International Accreditation Forum (IAF) provides useful guidance for the transition for all users of the standards, see
 - [IAF ID 9: 2015 Transition planning Guidance for ISO 9001:2015](#)

 - [IAF ID 10: 2015 Transition planning Guidance for ISO 14001:2015](#)

How to prepare for implementation of the new standards?

- Our recommendation is to start preparing for the transition as early as possible and plan properly to incorporate needed changes into your management system.
- **Recommended steps for the transition:**
 - Get to know the content and requirements of new standard. The standards, also the draft versions are available for purchase from ISO and possibly from your national standards provider. If you are a current user of the standards you should focus on the changes in requirements.
 - Ensure that relevant personnel in your organization are trained and understand the requirements and key changes.
 - Identify gaps which need to be addressed to meet the new requirements and establish an implementation plan.
 - Implement actions and update your management system to meet the new requirements.



How can DNVGL support your implementation?

DNV GL can support through e.g.:

- Seminars, webinars, e-learning etc. where you typically learn about the revisions and where you get a basic overview of the content and key changes in the standards, the transition process etc
- Tutored training courses, in-company or public. The objective of these courses is to provide detailed insight to the content and changes and about the required steps for transition. These are modular courses where the level of detail can be tailored to your needs.
- Gap assessment (workshops) where we assess your management system against the requirements of the new standard and identify the gaps that need to be addressed. This will provide useful input to your process to comply with the new standard. The level of detail of such assessment can be tailored to your needs.

Please contact your local DNVGL office for more info!

See also info on www.dnvgl.com



A smoother transition AND sustainable business performance

“DNV GLs Next Generation Risk Based Certification approach naturally supports your transition to the new revision of ISO standards.”

- Audit with the **added features** of Next Generation Risk Based Certification:
 - Improve your management system’s ability to support your (long term) business goals.
 - Build more sustainable value over time.
- Our **auditors**:
 - Have excellent industry knowledge and audit skills.
 - Are trained to take a ‘broader view’.
 - Are prepared to interpret & make new requirements tangible.



Thank you!

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