ISO 9001:2015

Main changes in the world's most popular QMS standard

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We are a global classification, certification, technical assurance and advisory company

OUR PURPOSE

TO SAFEGUARD LIFE, PROPERTY AND THE ENVIRONMENT

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Global reach – local competence

150 years

300 offices

100 countries

16,000 employees

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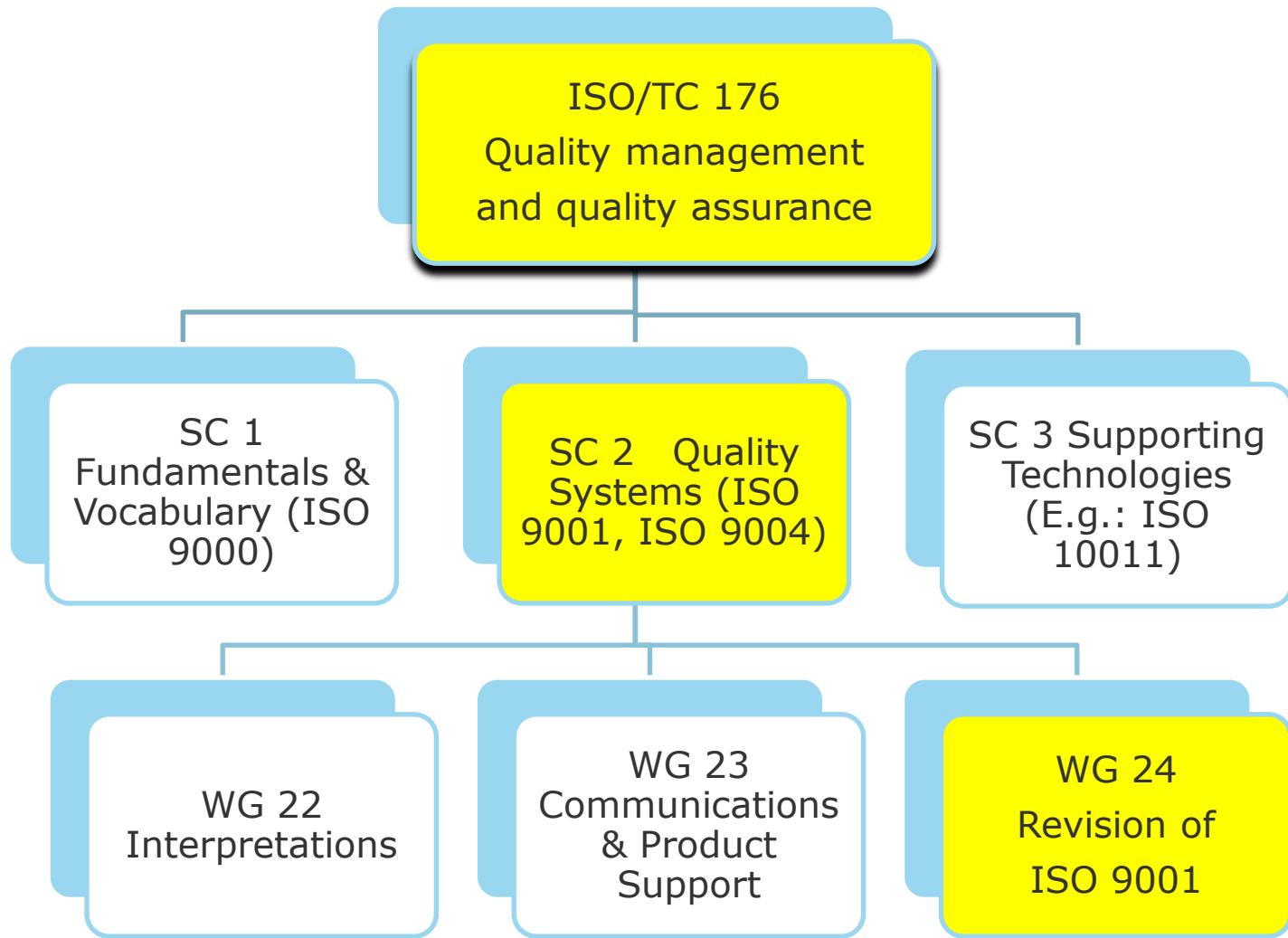
DNV GL :: Focused on your future

Tomorrow's successful companies will create value by meeting the world's **social, economic** and **environmental** needs.

We help you build **Sustainable Business Performance** through our global certification, verification, assessment and training services.

SUSTAINABLE VALUE and STAKEHOLDER TRUST

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ISO/TC 176

ISO/TC 176
Quality management
and quality assurance

SC 1 Fundamentals & Vocabulary (ISO 9000)

SC 2   Quality Systems (ISO 9001, ISO 9004)

SC 3 Supporting Technologies (E.g.: ISO 10011)

WG 22 Interpretations

WG 23 Communications & Product Support

WG 24 Revision of ISO 9001

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ISO/TC 176/SC 2's vision is for its products (primarily ISO 9001 and ISO 9004) to be "recognized and respected worldwide, and used by organizations as an integral component of their sustainable development initiatives".

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High Level Structure (HLS, found in Annex SL)

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

- Unified High Level Structure
- Common Text and Terminology

The common framework is defined in <u>Appendix 3 of ISO/IEC Directives, Part 1 Annex SL</u> (see pages 131-140 in document)

> Individual management systems standard will add additional "discipline-specific" requirements as required

Applicable for new standards and upcoming revisions of existing standards

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ISO High Level Structure (common framework)

Key objectives for the **common framework**:

1. Standardization and effectiveness in standards development (for ISO Technical Committees)
2. Enhanced alignment and compatibility of standards

Main advantages through enhanced compatibility of standards

- Easier to implement new standards
- Easier to integrate different management systems
- Increased value for users
- Increased effectiveness in standard development for the technical committees

ISO 9001:2015 and ISO 14001:2015 standards have been adapted to the HLS framework.

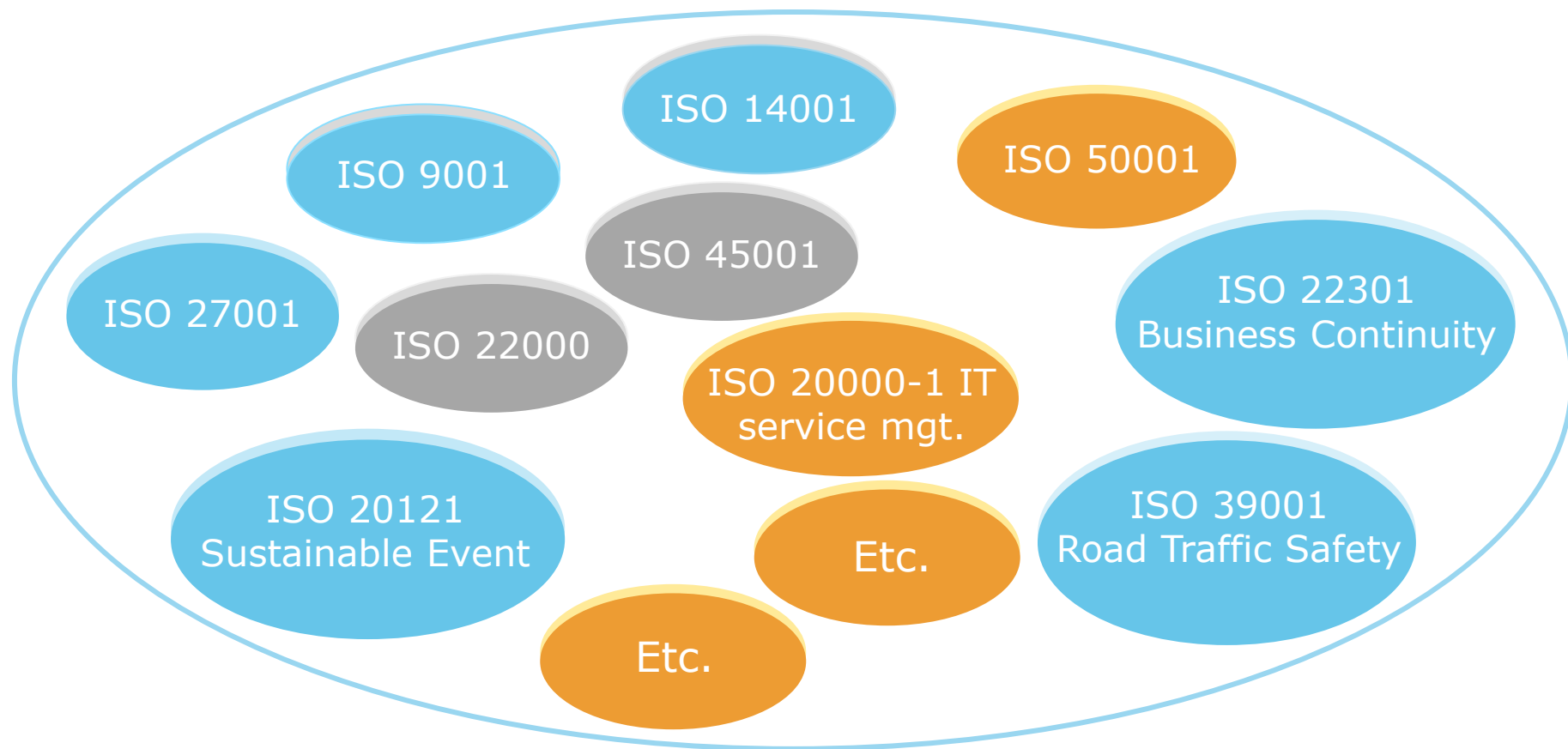# Annex SL - High Level Structure (HLS) – Main clauses

Introduction

1. Scope
2. Normative references
3. Terms and definitions
4. Context of the organization
5. Leadership

6. Planning
7. Support
8. Operation
9. Performance evaluation
10. Improvement.

Identical core text

For clauses 4-10 there are also sub-clauses, and identical core text (requirements) are provided (refer Appendix 3 in Annex SL).

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ISO Management System Standards

ISO 14001

ISO 9001

ISO 50001

ISO 45001

ISO 27001

ISO 22000

ISO 22301
Business Continuity

ISO 20000-1 IT service mgt.

ISO 20121
Sustainable Event

Etc.

ISO 39001
Road Traffic Safety

Etc.

Under revision/development following the HLS

Already published following the new High Level Structure
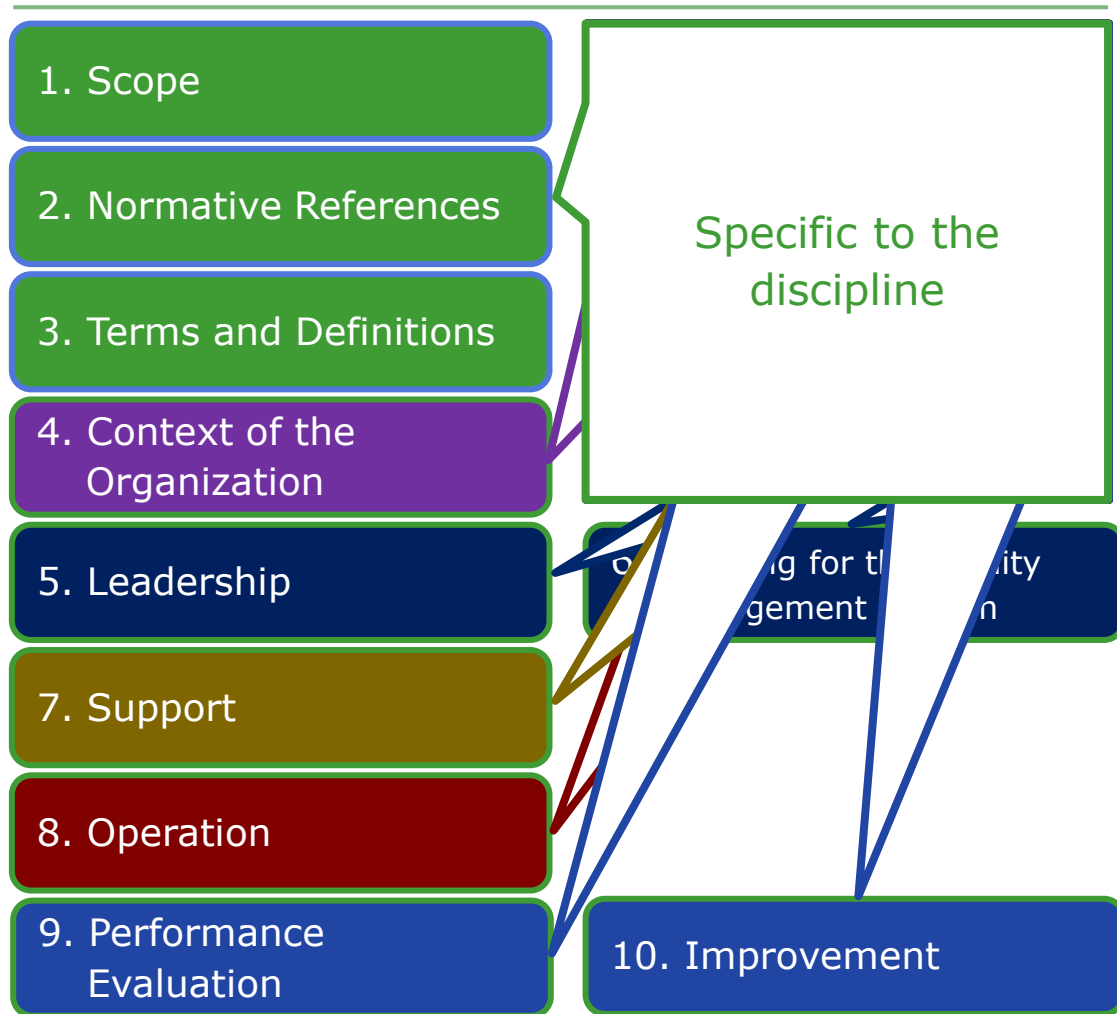
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Some Notable Changes

- **Risks and opportunities** – new concept, risk-based thinking

- Understanding the organization and its **context**

- Understanding the needs and expectations of **interested parties**

- **Top management** (_not_ a management representative) taking accountability for the effectiveness of the QMS

- **Objectives to be monitored** and planning more explicit, drivers for improvement

- **Effective resource management** – i.e. ensure availability of resources, more comprehensive emphasis

- **Systematic control of changes** of products and services

- 'Products' and 'Goods and Services' are replaced by **'Products and Services'**

- **Systematic release of products and services**

- **Documentation**
  - Required as necessary **for performance**
  - 'Documents and records' becomes '**documented information**'
  - No references to a **quality manual**

- **'Preventive action'** is removed

- Suppliers are now **'external providers'**

- Purchasing changed to **external provision of products and services**

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Comparing Clause Structures

ISO 9001:*2008*

- 1. Scope
- 2. Normative References
- 3. Terms and Definitions
- 4. Quality Management System
- 5. Management Responsibility
- 6. Resource Management
- 7. Product Realization
- 8. Measurement, Analysis and Improvement

ISO 9001:*2015*

- 1. Scope
- 2. Normative References
- 3. Terms and Definitions
- 4. Context of the Organization
- 5. Leadership
- 6. Planning for the quality management system
- 7. Support
- 8. Operation
- 9. Performance Evaluation
- 10. Improvement

Specific to the discipline

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Transition period from ISO 9001:2008 to ISO 9001:2015

Publication of the International Standard	Sept 15th 2015
Transition Period: 3 years from release date	Sept 15th 2018
All new certificates must be issued to ISO 9001:2015 from:	March 15th 2017
Can I recertify to ISO 9001:2008 after March 15th 2017?	

Until when can I maintain my new brand-new ISO 9001:2008 certification?

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New High Level Structure

ISO/IEC Directives, Part 1, Consolidated ISO Supplement, 2014 , Annex SL.9 & Appendix 2

1. Provide a core set of requirements (next 10+ years)

2. Focus on effective process management to produce desired outcomes (through leadership commitment and involvement)

3. Reflect changes in increasingly complex, demanding and dynamic environments (through identification of the context of the organization, its stakeholders & risk analysis)

4. Facilitate effective organizational implementation and effective conformity assessment by first, second and third parties

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1. Provide a Core Set of Requirements

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Core Set of Requirements

1	Scope

6	Planning

2	Normative References

7	Support

3	Terms and Definitions

8	Operation

4	Context of the Organization

9	Performance Evaluation

5	Leadership

10	Improvement

ISO 9001 additions

ISO 14001 additions

ISO 31000 additions

ISO 27001 additions

ISO 45001 additions

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2. Focus on Effective Process Management

High Level Structure

Focuses on effective process management to produce desired outcomes (through leadership commitment and involvement)

5	Leadership

5.1 Leadership and commitment

5.2 Policy

5.3 Roles, responsibility & authority

6	Planning

6.1 Actions to address risks and opportunities

6.2 XXX objectives and planning to achieve them
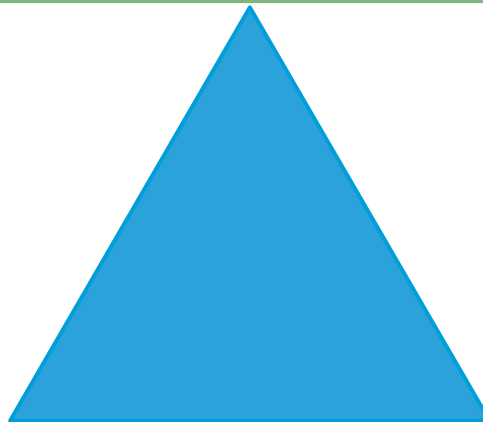
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Leaders and Managers

- Planning and budgeting
- Organizing and staffing
- Controlling and problem solving
- Taking complex systems of people and technology and making them run efficiently and effectively, hour after hour, day after day

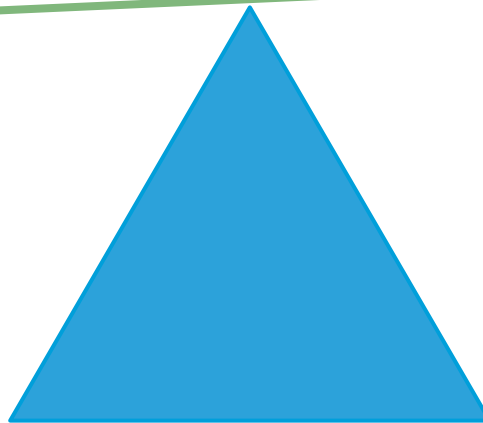**Leader**   **Manager**

Leaders and Managers

- Creating vision and strategy
- Communicating and setting direction
- Motivating action
- Aligning people
- Creating systems that managers can manage, transforming them when needed to allow for growth, evolution, opportunities, and hazard avoidance

- Planning and budgeting
- Organizing and staffing
- Controlling and problem solving
- Taking complex systems of people and technology and making them run efficiently and effectively, hour after hour, day after day

Manager

Leader

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Leadership

Leadership issues are addressed in several clauses. New, or clarified, issues are:

- Connection of **management system to strategy** and business processes **(5.1)**

- Aim and **intended output** of the management system **(4.1, 5.1, 5.3, 6.1)**

- Principles of '**result-based management** / management by objectives' **(5.1, 6.2)**

- Systematic **change management (8.1)**

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5.1 Leadership and Commitment

- Top management is responsible for the **effective implementation** of the management system.

  – The requirement for a **management representative** is not present.

- There must be a clear link between the **business plan and the management system** (policy, goals, etc..).

- Management system is coupled to the business processes and its **expected outcome**.

3. Reflect Changes in Dynamic Environments

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High Level Structure

- **Reflect changes** in the increasingly complex, demanding and dynamic environments (through identification of the context of the organisation, its stakeholders & risk analysis)

4	Context of the organization

4.1 Understanding the organization and its context

4.2 Understanding the needs and expectations of interested parties

4.3 Determining the scope of the XXX management system

4.4 XXX Management system

Interested Parties

- Employees
- Investors
- Customers
- Suppliers
- Business Partners
- Host Communities
- Competitors & peers
- Contractors
- Government & regulators
- Banks/Insurance
- NGOs & pressure groups
- The Media
- Opinion Leaders
- Scientific community
- Certification Bodies
- Neighbors

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Interested Parties (Stakeholders): Growing Importance

A organization **should not take for granted its relationships** with employees, customers, investors, suppliers, business partners etc.

The **better its relationship** with stakeholders, the more likely they will:

- Want to **work** for the company
- **Buy** its products
- Want to be its business **partner** / supplier
- **Invest** in the company
- **Lend** it money
- Have it as part of their **community,** etc.

Stakeholders can grant a company its '**social license to operate'** (or they can take it away)

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4. Facilitate Sustainable Business Development

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High Level Structure

- Facilitate **Sustainable Business Development**

4	Context of the Organization

4.1 Understanding the organization and its context

4.2 Understanding the needs and expectations of interested parties

6	Planning

6.1 Actions to address <u>risks</u> and <u>opportunities</u>

6.2 XXX objectives and planning to achieve them

Your Next Steps

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Step by Step Transition

Identify Key Changes

- Understand the new requirements
- Training

Perform Gap Analysis

- Gap Assessment

Plan and Do

- Planning for critical activities
- Implementation strategies
- Management commitment

Check

- Internal audits
- Management Review
- External audit (if certified)

Act

- Improvement Strategies

1   2   3   4   5

DNV GL Workshop : Transition Strategies for ISO 9001:2015

- Comprehensive review of the new clauses and common core

- Key changes in ISO 9001:2015

- How the new standards fit in our global risk reality

- January 14   Long Beach, CA

- February 5   Houston, TX

- *Week March 1* San Jose, CA; Portland, OR; Gresham, ID*

- March 8   Phoenix, AZ

- May 20   Long Beach, CA

- June 9   Houston, TX

(*) Tentative pending venue confirmation.
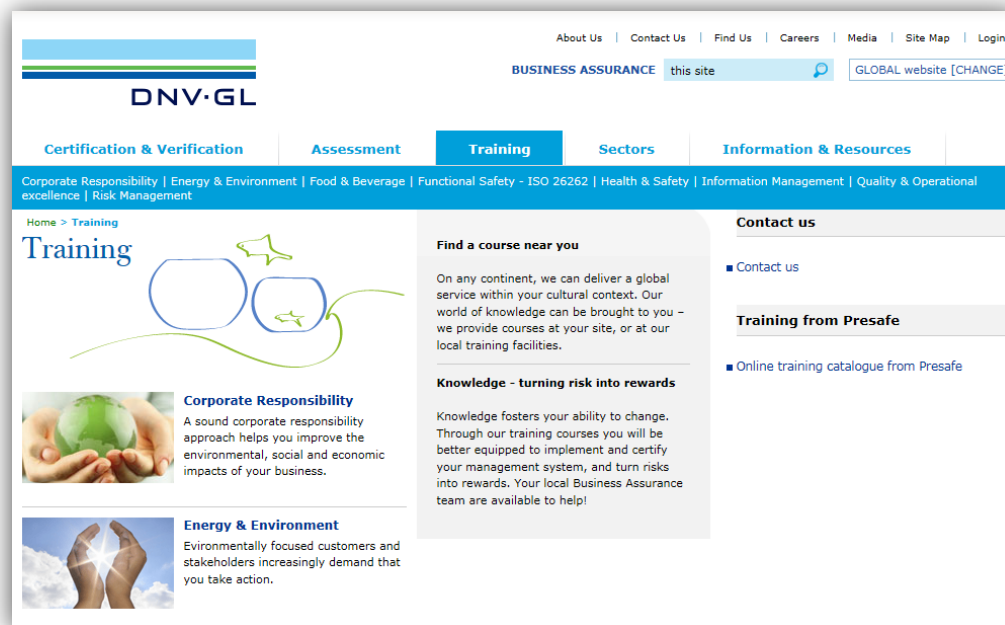
Questions

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Thank You!

Burt.Holm@dnvgl.com   (804) 413-2032

Manuel.Marco@dnvgl.com   (949) 521-0298

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