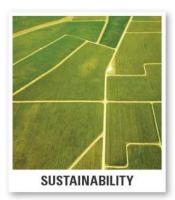




FURTHER EXCELLENCE







ISO 9001 REVISION INTRODUCTION TO ISO 9001: 2015







Introduction

- Structure and Terminology
- Changes to ISO 9001
- Future Developments
- How SGS can support you





ISO/DIS 9001

Issued May 2014

ISO/FDIS 9001

Issued July 2015

ISO 9001: 2015

Issued September 2015

Final stage in the revision process



ISO 9001: 2015 adopts Annex SL Framework

- Standardized structure format
- Incorporates common
 - Definitions
 - Text and requirements in many areas

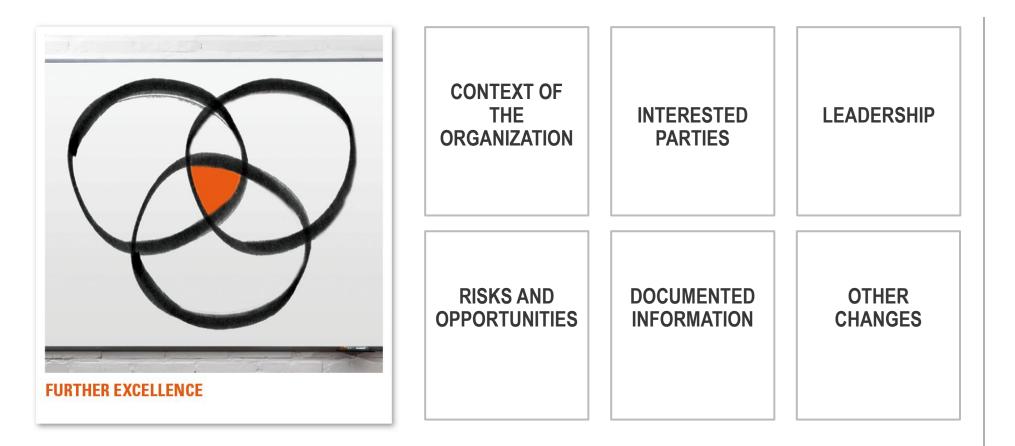


- 1. Scope
- 2. Normative references
- 3. Terms and definitions
- 4. Context of the organization
- 5. Leadership
- 6. Planning
- 7. Support
- 8. Operation
- 9. Performance evaluation
- 10. Improvement



ISO 9001: 2008	ISO 9001: 2015
'Products'	'Products and services'
'Documentation' 'Records'	'Documented information'
'Work environment'	'Environment for the operation of processes'
'Purchased product'	'Externally provided processes, products and services'
'Supplier'	'External provider'
'Preventive Action'	N/A
'Exclusions'	N/A







A Quality Management System (QMS) cannot exist in isolation

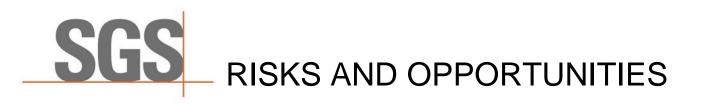
- Internal and external issues
- Interested parties
- QMS scope of applicability
- Risks and opportunities these represent



- Who are the 'interested parties' relevant to an organizations QMS?
- What are their needs and expectations?
- How does an organization establish who and what they are?
- What ongoing review of the 'who' and 'what' takes place?



- Now an emphasis on leadership rather than simply management
- More direct involvement in an organization's QMS
- Specific 'Management Representative' no longer required



- What risks and opportunities have the potential to impact (negatively or positively) on the operation and performance of an organization's QMS.
- What action needs to be taken to:
 - Remove or reduce risks
 - Take advantage of opportunities



No longer any specific requirements relating to a Quality Manual or to documented procedures

Terms 'documented procedure' and 'record' used in have both been replaced throughout ISO 9001: 2015 by the term 'documented information'



- Process approach
- Competence
- Organizational knowledge
- External provision of goods and services
- Preventive action



- The ISO 9001: 2015 requirements encourage organizations to use more external focus in a broader risk-based approach to Quality Management
- Adoption of the Annex SL framework will help with alignment and integration of other management system standards
- Gives greater flexibility to individual organization's QMS structure and content



Organizations already certified to ISO 9001:2008 will have three years in which to transfer to the new version of the Standard.

Based on the final publication date, this transition period would end September 2018.



Training

- ISO 9001: 2015
- Annex SL IRCA approved CPD course
- Risk-Based Thinking –IRCA approved CPD course
- Empowering Leadership
- Needs Assessment/Gap Analysis
- Certification







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WHEN YOU NEED TO BE SURE