ISO 9001 REVISION
INTRODUCTION TO ISO 9001: 2015

FURTHER EXCELLENCE

WHEN YOU NEED TO BE SURE
AGENDA

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

- ISO/DIS 9001
  - Issued May 2014
- ISO/FDIS 9001
  - Issued July 2015
- ISO 9001: 2015
  - Issued September 2015
- Final stage in the revision process
STRUCTURE & TERMINOLOGY

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

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
# TERMINOLOGY

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>‘Products’</td>
<td>‘Products and services’</td>
</tr>
<tr>
<td>‘Documentation’ ‘Records’</td>
<td>‘Documented information’</td>
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<tr>
<td>‘Work environment’</td>
<td>‘Environment for the operation of processes’</td>
</tr>
<tr>
<td>‘Purchased product’</td>
<td>‘Externally provided processes, products and services’</td>
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<tr>
<td>‘Supplier’</td>
<td>‘External provider’</td>
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<tr>
<td>‘Preventive Action’</td>
<td>N/A</td>
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<tr>
<td>‘Exclusions’</td>
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CHANGES TO ISO 9001

CONTEXT OF THE ORGANIZATION

INTERESTED PARTIES

LEADERSHIP

RISKS AND OPPORTUNITIES

DOCUMENTED INFORMATION

OTHER CHANGES

FURTHER EXCELLENCE
ORGANIZATIONAL CONTEXT

- 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 organization’s 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?
LEADERSHIP

- Now an emphasis on leadership rather than simply management
- More direct involvement in an organization’s QMS
- Specific ‘Management Representative’ no longer required
RISKS AND OPPORTUNITIES

- 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
DOCUMENTED INFORMATION

- 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’
OTHER CHANGES

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

- 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.
FUTURE DEVELOPMENT

- 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.
SGS SOLUTIONS FOR A SMOOTH TRANSITION

- Training
  - ISO 9001: 2015
  - Annex SL – IRCA approved CPD course
  - Risk-Based Thinking – IRCA approved CPD course
  - Empowering Leadership

- Needs Assessment/Gap Analysis

- Certification
WHY WORK WITH SGS?

- LARGEST PROVIDER OF AUDITS, CERTIFICATION AND PERFORMANCE ASSESSMENTS
- LOCAL AND INTERNATIONAL PROJECT MANAGEMENT
- MOST WIDELY ACCREDITED CERTIFICATION BODY
- EXPERIENCED AND RESULTS-ORIENTED AUDITORS AND TUTORS
- WORLDWIDE NETWORK
- IMPARTIAL AND INDEPENDENT

FURTHER EXCELLENCE
HOW WE BUILD STAKEHOLDER VALUE

SGS SOLUTIONS – BUILDING STAKEHOLDER VALUE

MANAGEMENT SYSTEMS COMPLIANCE
Audit and certification services for compliant processes and management systems

PERFORMANCE ASSESSMENTS
Tailored assessments for internal and external improvement and transparency

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