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# 2015 updates to ISO9001 and ISO14001

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# Agenda

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- Introduction to Ingenious Quality
- Background to ISO changes and Annex SL
- Timeline for change to new standards
- Details of main changes to the standards
- What to do next?
- Questions
- Appendices: Detailed tables of correspondence (ISO9001 + ISO14001)

# Ingenious Quality Ltd Intro.

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- ❑ A management consultancy set up in 2005 to serve the needs of the electronics industry
- ❑ Over 30 years experience in the electronics industry in the UK, Europe and USA
- ❑ Specialist in introduction and support of
  - Quality management systems (ISO9001)
  - Product quality improvement, qualification and reliability
  - Environmental management systems (ISO14001)
  - H&S management systems (BS OHSAS18001>ISO 45001)
  - Business continuity management systems (ISO22301)

# Background to changes

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- ❑ All ISO management standards are changing format to align paragraph numbering and content in accordance with Annex SL
- ❑ All standards will have the same 10 section titles with only the content differing
- ❑ Last major revision to ISO9001 was 2000 with a minor tweak in 2008; last ISO14001:2004
- ❑ ISO committee decided to start revisions in 2012
- ❑ Recognition of increasing number of non-manufacturing businesses adopting the standards

# Annex SL and old Contents

*(Lists not cross ref. table)*

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## **Annex SL (all new stds.)**

1. Scope
2. Normative references
3. Terms and definitions (13 pages)
4. Context of the organisation
5. Leadership
6. Planning
7. Support
8. Operation
9. Performance evaluation
10. Improvement

## **ISO9001:2008**

1. Scope
2. Normative references
3. Terms and definitions (1 line)
4. Quality management system
5. Management responsibility
6. Resource management
7. Product realisation
8. Measurement, analysis and improvement

## **ISO14001:2004**

1. Scope
2. Normative references
3. Terms and definitions (2.5 pages)
4. Environmental management system requirements

# ISO 9001/14001 Timelines

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- ❑ Draft ISO9001 and 14001 standards are available from standards bodies *now* (9001 was 27 pages; now 52 pages)
- ❑ Full ISO9001 standard is due to be published Sept 15
- ❑ Full ISO14001 standard is due to be published Jan 15
- ❑ Don't need to make any changes until after these dates but can move towards new system now
- ❑ There will be a 3 yr. transition period allowed for full compliance to the new revision

# Main changes to ISO9001

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- ❑ Quality Manual and 6 mandatory procedures no longer required:
  - ❑ Document control
  - ❑ Internal audit
  - ❑ Control of non-conforming product
  - ❑ Corrective action
  - ❑ Preventive action
  - ❑ Control of records
- ❑ Movement from “documents” and “records” to “documented information” which aligns more to electronic information systems

# Main changes to ISO9001 cont.

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- Terminology
  - “Product” replaced with “products and services”
  - “Purchasing” or “outsourcing” replaced with “external provision of products and services”
- Increased emphasis on “risk management” in place of “preventive action”



# Main changes to ISO9001 cont.

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- Requiring systems which take into account the “context of the organization” which implies a broader measurement, planning and implementation view
  - Business environment, business ecosystem: whether public service, not-for-profit or regular business
- Increased involvement of senior management
  - Need to understand business strategy and link to Quality Policy

# What next?

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- ❑ You can still apply for certification under the current standards if not already certified
- ❑ Continue to run and maintain your existing management systems to current requirements
- ❑ Don't ditch the mandatory procedures or Quality Manual as you move forwards!

# What next? cont.

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- Ensure that your top management is involved in your management system and understands that they will need to demonstrate this to auditors
  - Recent EEF survey of 650 companies indicated that 40% say top management have little or no involvement in their EMS
- Start to determine your risk management strategies and methods to emphasise preventive action

# What next? cont.

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- ❑ Consider the application of Business continuity management systems –Requirements (ISO22301:2014) which follows the new format and also emphasises risk management and will complement/prepare your ISO 9001 and 14001 management systems for 2015
- ❑ Increasingly being asked for by tier 1 customers and insurance companies

# Questions?

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- Thanks for listening!

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Appendix A

# **ISO9001 DETAILED CORRESPONDENCE TABLE**

# Correspondence between ISO/DIS 9001:2015 and ISO 9001:2008

ISO/DIS 9001:2015		ISO 9001:2008	
Context of the organization (title only)	4	1.0	Scope
Understanding the organization and its context	4.1	1.1	General
Understanding the needs and expectations of interested parties	4.2	1.1	General
Determining the scope of the quality management system	4.3	1.2 4.2.2	Application Quality manual
Quality management system and its processes	4.4	4 4.1	Quality management system General requirements

# Correspondence between ISO/DIS 9001:2015 and ISO 9001:2008

ISO/DIS 9001:2015		ISO 9001:2008	
<b>Leadership</b>	<b>5</b>	<b>5</b>	<b>Management responsibility</b>
Leadership and commitment	5.1	5.1	Management commitment
Leadership and commitment	5.1	5.1	Management commitment
Leadership and commitment for the quality management system	5.1.1	5.1	Management commitment
Customer focus	5.1.2	5.2	Customer focus
Quality policy	5.2	5.3	Quality policy
Organizational roles, responsibilities and authorities	5.3	5.5.1 5.5.2	Responsibility and authority Management representative



# Correspondence between ISO/DIS 9001:2015 and ISO 9001:2008

ISO/DIS 9001:2015		ISO 9001:2008	
<b>Planning for the QMS</b>	<b>6</b>	<b>5.4.2</b>	<b>QMS Planning</b>
Actions to address risks and opportunities	6.1	5.4.2	Quality management system planning
		8.5.3	Preventive action
Quality objectives and planning to achieve them	6.2	5.4.1	Quality objectives
Planning of changes	6.3	5.4.2	Quality management system planning
<b>Support</b>	<b>7</b>	<b>6</b>	<b>Resource management</b>
Resources	7.1	6	Resource management
General	7.1.1	6.1	Provision of resources
People	7.1.2	6.1	Provision of resources
Infrastructure	7.1.3	6.3	Infrastructure

# Correspondence between ISO/DIS 9001:2015 and ISO 9001:2008

ISO/DIS 9001:2015		ISO 9001:2008	
Environment for the operation of processes	7.1.4	6.4	Work environment
Monitoring and measuring resources	7.1.5	7.6	Control of monitoring and measuring equipment
Organizational knowledge	7.1.6		New
Competence	7.2	6.2.1 6.2.2	General Competence, training and awareness
Awareness	7.3	6.2.2	Competence, training and awareness
Communication	7.4	5.5.3	Internal communication
Documented information	7.5	4.2	Documentation requirements
General	7.5.1	4.2.1	General

# Correspondence between ISO/DIS 9001:2015 and ISO 9001:2008

ISO/DIS 9001:2015		ISO 9001:2008	
Creating and updating	7.5.2	4.2.3 4.2.4	Control of documents Control of records
Control of documented information	7.5.3	4.2.3 4.2.4	Control of documents Control of records
<b>Operation</b>	<b>8</b>	7	Product realization
Operational planning and control	8.1	7.1	Planning of product realization
Determination of requirements for products and services	8.2	7.2	Customer-related processes
Customer communication	8.2.1	7.2.3	Customer communication
Determination of requirements related to products and services	8.2.2	7.2.1	Determination of requirements related to the product

# Correspondence between ISO/DIS 9001:2015 and ISO 9001:2008

ISO/DIS 9001:2015		ISO 9001:2008	
Review of requirements related to the products and services	8.2.3	7.2.2	Review of requirements related to the product
Design and development of products and services	8.3	7.3	Design and development
General	8.3.1		New
Design and development planning	8.3.2	7.3.1	Design and development planning
Design and development Inputs	8.3.3	7.3.2	Design and development inputs
Design and development controls	8.3.4	7.3.4	Design and development review
		7.3.5	Design and development verification
		7.3.6	Design and development validation

# Correspondence between ISO/DIS 9001:2015 and ISO 9001:2008

ISO/DIS 9001:2015		ISO 9001:2008	
Design and development outputs	8.3.5	7.3.3	Design and development outputs
Design and development changes	8.3.6	7.3.7	Control of design and development changes
Control of externally provided products and services	8.4	7.4.1	Purchasing process
General	8.4.1	7.4.1	Purchasing process
Type and extent of control of external provision	8.4.2	7.4.1 7.4.3	Purchasing process Verification of purchased product
Information for external providers	8.4.3	7.4.2	Purchasing information
Production and service provision	8.5	7.5	Production and service provision
Control of production and service provision	8.5.1	7.5.1	Control of production and service provision

# Correspondence between ISO/DIS 9001:2015 and ISO 9001:2008

ISO/DIS 9001:2015		ISO 9001:2008	
Identification and traceability	8.5.2	7.5.3	Identification and traceability
Property belonging to customers or external providers	8.5.3	7.5.4	Customer property
Preservation	8.5.4	7.5.5	Preservation of product
Post-delivery activities	8.5.5	7.5.1	Control of production and service provision
Control of changes	8.5.6	7.3.7	Control of design and development changes
Release of products and services	8.6	8.2.4	Monitoring and measurement of processes
		7.4.3	Verification of purchased product
Control of nonconforming process outputs, products and services	8.7	8.3	Control of nonconforming product

# Correspondence between ISO/DIS 9001:2015 and ISO 9001:2008

ISO/DIS 9001:2015		ISO 9001:2008	
<b>Performance evaluation</b>	<b>9</b>		New
Monitoring, measurement, analysis and evaluation	9.1	8	Measurement, analysis and improvement
General	9.1.1	8.1	General
Customer satisfaction	9.1.2	8.2.1	Customer satisfaction
Analysis and evaluation	9.1.3	8.4	Analysis of data
Internal audit	9.2	8.2.2	Internal audit
Management review	9.3	5.6	Management review
<b>Improvement</b>	<b>10</b>	8.5	Improvement
General	10.1	8.5.1	Continual improvement
Nonconformity and corrective action	10.2	8.3 8.5.2	Control of nonconforming product Corrective action
Continual improvement	10.3	8.5.1	Continual improvement

Appendix B

# **ISO14001 DETAILED CORRESPONDENCE TABLE**



# Correspondence between ISO/DIS 14001:2015 and ISO 14001:2004

ISO/DIS 14001:2015		ISO 14001:2004	
Context of the organization (title only)	4		
Understanding the organization and its context	4.1		
Understanding the needs and expectations of interested parties	4.2		
Determining the scope of the environmental management system	4.3	4.1	General requirements
Environmental management system	4.4	4.1	General requirements

# Correspondence between ISO/DIS 14001:2015 and ISO 14001:2004

ISO/DIS 14001:2015		ISO 14001:2004	
<b>Leadership and commitment</b>	<b>5.1</b>		
Environmental policy	5.2	4.2	Environmental policy
Organizational roles, responsibilities and authorities	5.3	4.4.1	Resources, roles, responsibility and authority
<b>Planning (title only)</b>	<b>6</b>	<b>4.3</b>	<b>Planning (title only)</b>
Actions to address risk associated with threats and opportunities (title only)	6.1		
General	6.1.1		
Significant environmental aspects	6.1.2	4.3.1	Environmental aspects

# Correspondence between ISO/DIS 14001:2015 and ISO 14001:2004

ISO/DIS 14001:2015		ISO 14001:2004	
Compliance obligations	6.1.3	4.3.2	Legal and other requirements
Risk associated with threats and opportunities	6.1.4		
Planning to take action	6.1.5		
Environmental objectives and planning to achieve them (title only)	6.2	4.3.3	Objectives, targets and programme(s)
Environmental objectives	6.2.1	4.3.3	Objectives, targets and programme(s)
Planning actions to achieve environmental objectives	6.2.2	4.3.3	Objectives, targets and programme(s)
<b>Support (title only)</b>	<b>7</b>	4.4	Implementation and operation (title only)
Resources	7.1	4.4.1	Resources, roles, responsibility and authority

# Correspondence between ISO/DIS 14001:2015 and ISO 14001:2004

ISO/DIS 14001:2015		ISO 14001:2004	
Competence	7.2	4.4.2	Competence, training and awareness
Awareness	7.3	4.4.2	Competence, training and awareness
Communication (title only)	7.4	4.4.3	Communication
General	7.4.1	4.4.3	Communication
Internal communication	7.4.2	4.4.3	Communication
External communication	7.4.3	4.4.3	Communication
Documented information (title only)	7.5	4.4.4	Documentation
General	7.5.1	4.4.4	Documentation

# Correspondence between ISO/DIS 14001:2015 and ISO 14001:2004

ISO/DIS 14001:2015		ISO 14001:2004	
Creating and updating	7.5.2	4.4.5	Control of documentation
		4.5.4	Control of records
Control of documented information	7.5.3	4.4.5	Control of documentation
		4.5.4	Control of records
<b>Operation (title only)</b>	<b>8</b>	4.4	Implementation and operation (title only)
Operational planning and control	8.1	4.4.6	Operational control
Emergency preparedness and response	8.2	4.4.7	Emergency preparedness and response

# Correspondence between ISO/DIS 14001:2015 and ISO 14001:2004

ISO/DIS 14001:2015		ISO 14001:2004	
<b>Performance evaluation (title only)</b>	<b>9</b>	4.5	Checking (title only)
Monitoring, measurement, analysis and evaluation (title only)	9.1	4.5.1	Monitoring and measurement
General	9.1.1	4.5.1	Monitoring and measurement
Evaluation of compliance	9.1.2	4.5.2	Evaluation of compliance
Internal audit	9.2	4.5.5	Internal audit
Management review	9.3	4.6	Management review
<b>Improvement (title only)</b>	<b>10</b>		
Nonconformity and corrective action	10.1	4.5.3	Nonconformity, corrective action and preventive action
Continual improvement	10.2		