LMS Certifications Pvt. Ltd.

ISO 9001 and ISO 14001 Transition

Objective

- Section 1: presentation of LMS's interpretation of the high level structure of Annex SL;

- Section 2: To provide an overview of the changes in the 2015 version of the ISO 9001 and ISO 14001 standards;

- Section 3: To compare the changes and present them side-by-side for a better understanding of integration and standard languages effectiveness of the standards;

- Section 4: How do we move forward

Annexe XL and
ISO 9001 & ISO 14001:2015
Awareness and Orientation

What this session will cover:

- What is Annex SL – A brief explanation

- Reasons for its introduction

- Summary of identified changes in comparison with current edition of ISO 9001/ISO 14001.

- Putting Annex SL into context

- The use of management system standards – some comments on influencing factors for consideration.

- Exposing and understanding Annex SL

- How will Annex SL affect business?

- How will Annex SL affect certification?

- Conclusions

Annex SL (Appendix 2)

A framework for all ISO management system standards (MSS) providing:

- high level structure (HLS)

- identical sub clause titles

- identical text

- common terms and core definitions

Why was Annex SL introduced?

1. To create a common text framework, which will be easier for organisations to utilise and for auditors to audit against.

2. To improve the effectiveness, and value of management system standards generally by being more holistic.

Summary of key changes identified in Annex SL

4. Context of the Organisation

4.1 – Understanding the organisation and its context to internal and external issues

4.2 – Understand the needs and expectations of interested parties.

4.3 – Determining the scope of the XXX management system.

5. Leadership.

This is a change in term, as it was previously 'Management responsibility'.

 Note:

ensuring that the XXX policy and XXX objectives are established and are compatible with the **strategic direction** *of the organization*

directing and supporting persons to contribute to the effectiveness of the XXX management system

6. Planning

6.1 Actions to address risks and **opportunities**

Also of note : the absence of 'preventive action'.

7. Support.

This section has grouped a number of clauses. ie:-
'responsibility and authority and communication' and
'resource management'.

Most notable change is in relation to documentation.
The

requirements are limited . There is no requirement for
documented procedures of any kind.

8. Operation

This section is an example of how the current versions of the standards do not align well.

If you are more familiar with ISO 14001, then you might be thinking 4.4.6 - Operational control. If you are more familiar with ISO 9001, then you might be thinking about "Clause 7 (7.1 Planning of product realisation, right through to – 7.5.5 Preservation of produce)".

So, there is a reorganisation and standardisation of clauses and terms.
As an example of how scheme specific clauses will be incorporated, in 14001 "Emergency planning and response" is included here.

9. Performance Evaluation

10. Improvement

The content of both of these sections is largely familiar.

The use of Management System Standards

Standards are produced for businesses to use and benefit from

Organisations that embrace management systems benefit from them.

But there are organisations that just want the certificate.

- The Management System is a superficial overlay.

- The Management System is seen as a pain

- Disconnect between Senior Management and Management System

The superficial adoption of management systems devalues management systems globally.

Certification

- Whilst the standards are written for business, and not for auditors, certification is a very important area, directly tied to the utilisation of management systems.

- The value of certification can therefore directly impact on the actual value and perceived value of management system standards.

- There is pressure on the Certification bodies to accept 'superficial adoption' of the management system standards, as it is a very competitive market.

Auditor Competence

- Wrapped up within the Certification elements is 'auditor competence'. This has been a topic of increasing prevalence, and ISO 17021:2011 highlights that it is has been considered an area that needed to be addressed.

- Poor auditors devalue certification, which in turn devalues management system standards.

- But ISO is not in control or involved with prescribing what auditor competence is. That is all up to the Certification Bodies and Accreditation Bodies – or is it?

Silo approach

- Due to standards being produced separately, and with different structures and different terminology, ISO has perhaps, historically, promoted the thinking that management systems are independent from one another.

- In reality a business has one management system. The 'business management system'.

Exposing Annex SL

A lot of the changes noted earlier, such as 'context of the organisation' and internal and external issues, and interested parties, and leadership and risks and opportunities are actually all linked.

These clauses are insisting that the management system is **not** held at arms length. They very neatly tie the management system to the strategic direction of the business, to the senior management of the business, and require that the business 'orientates' itself effectively.

Annex SL is raising the standards into the board room

Annex SL is aligning standards with the needs of business.

General approach (not silo), considering MS in relation to business more holistically.

Light documented requirements

Development in 9001 – as examples.

Trying to restrict limited scopes

How will it affect Business?

- For organisations that embrace the management system standards, there will be likely very little effect.

- Annex SL puts pressure on organisations that take a superficial approach and perhaps are only 'interested in the certificate'.

- The clauses have made it less easy to hold the system at arm's length and put pressure on the organisation to utilise the standards the way that they were originally intended.

How will it affect Certification?

- If LMS accept that currently, there are auditors adding little value to organisations because they are conducting 'eyes down', tick list like audits, then we have a competence gap'.

- Auditors need to be more business minded and experienced with management in order to provide business with value.

Annex SL places pressure on the certification bodies to reconsider 'what an acceptable scope or boundary of a management system is' as the standards will require a more holistic approach, that should make it more difficult to have very deliberately limited scopes.

Certification Bodies may not want to change anything, as the changes may make in more difficult to issue certificates to organisations doing a superficial job if implementation.

LMS will consider their context currently, and the 'risks and opportunities' that exist to them. With that information, determine whether there may be any advantage in proactively tackling the issues presented here, to position themselves as a the market leader in this regard.

Conclusions

- Annex SL is a lot more than just a common framework for Management System Standards.

- The new Clauses are intending to align standards with business.

- The new clauses intend to help stop the devaluing of management system standards through superficial adoption, low level auditing and meaningless certification.

- Annex SL, will require an increase in auditor competence, if certification is to be seen to   be beneficial to business.
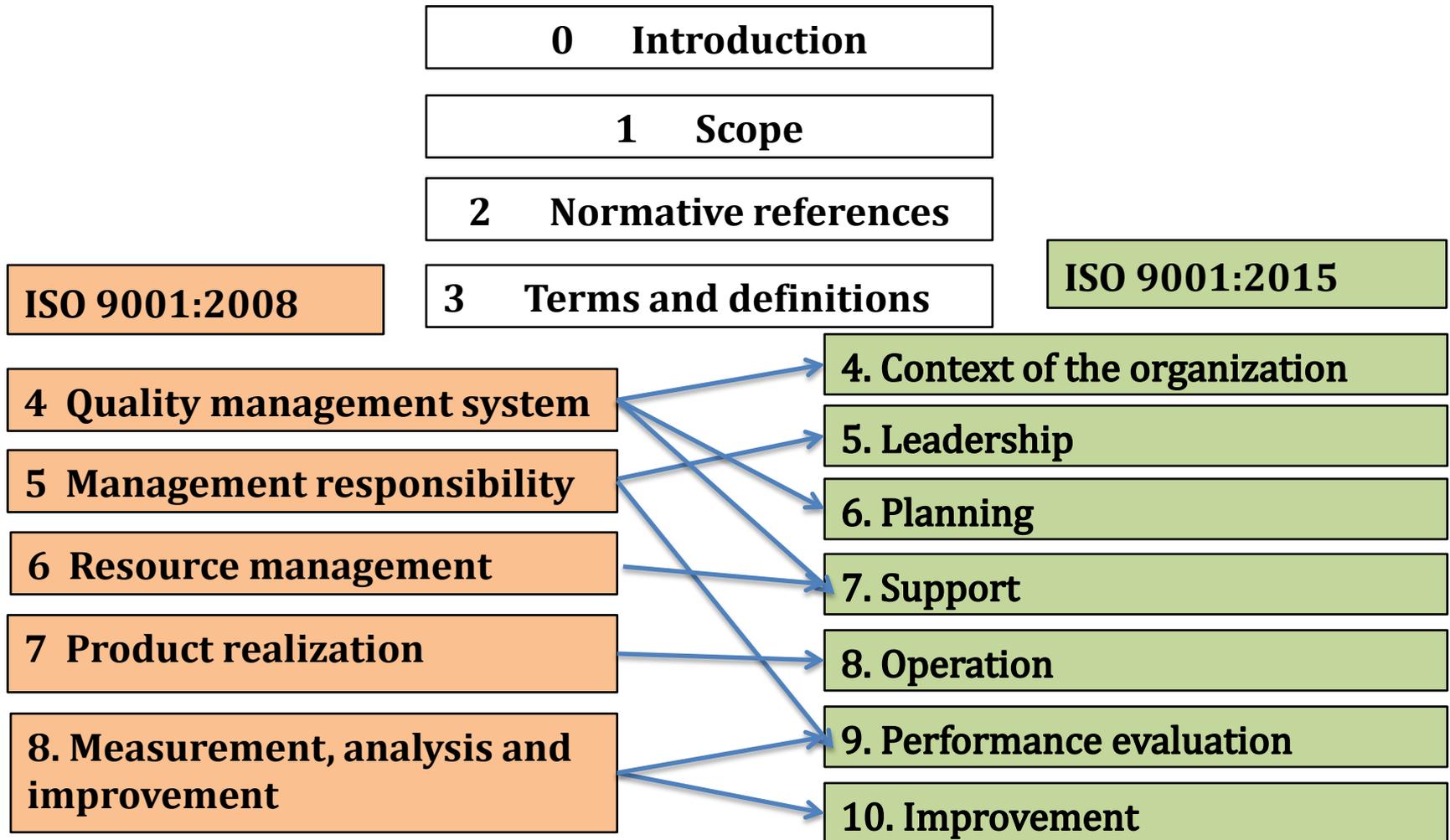
SECTION 2

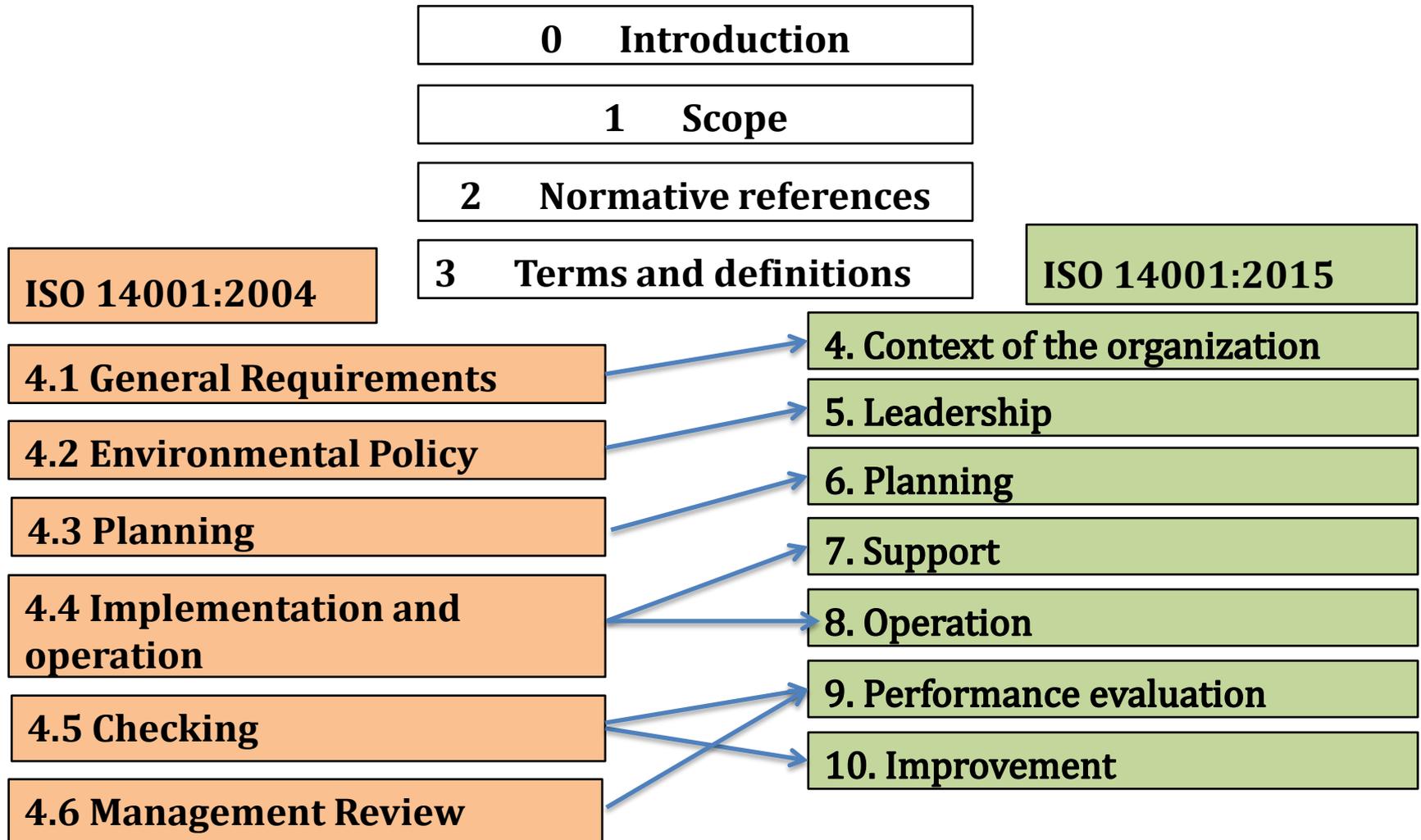# OVERVIEW OF THE CHANGES IN THE 2015 VERSIONS OF ISO9001 AND 14001

Comparing ISO 9001

0	Introduction

1	Scope

2	Normative references

3	Terms and definitions

ISO 9001:2008

ISO 9001:2015

ISO 9001:2008	ISO 9001:2015
4 Quality management system	4. Context of the organization
5 Management responsibility	5. Leadership
6 Resource management	6. Planning
7 Product realization	7. Support
8. Measurement, analysis and improvement	8. Operation
	9. Performance evaluation
	10. Improvement

Comparing ISO 14001

0	Introduction
1	Scope
2	Normative references
3	Terms and definitions

ISO 14001:2004

ISO 14001:2015

ISO 14001:2004	ISO 14001:2015
4.1 General Requirements	4. Context of the organization
4.2 Environmental Policy	5. Leadership
4.3 Planning	6. Planning
4.4 Implementation and operation	7. Support
	8. Operation
4.5 Checking	9. Performance evaluation
4.6 Management Review	10. Improvement

Big changes - Common

- Standards follow the high level structure of **Annex SL**;
- **No procedures mandated**. Procedures to be made when the lack can cause non-conformance;
- Extent of documentation adequate to provide demonstrability and confidence;
- Documentation referred to as 'documented information';
- Concepts of established/documented procedures, documents, records removed;
- Broadly: When the standard says
  - _maintain_ documented information, it is about 'document' of the previous terminology;
  - _retain_ documented information, it is about 'record' of the previous terminology.
- _Preventive Action_ as a term removed from the main body of the standard. Risk based thinking and context of the organization replace this.

Big changes – ISO 9001

- **Risk** based thinking brought in;

- **Supplier** indicated as **external provider;**

- **Exclusion** as concept has been excluded in the ISO 9001 standard. (The organization can only decide that a requirement is not applicable if its decision will not result in failure to achieve conformity of products and services;

- **Products** become **products and services;**

- **Purchased product** become **externally provided products and services;**

- **Organizational knowledge** introduced.

ISO9001 and ISO14001 changes

A blue colour text is used to indicate changes in the requirements between the standards

4 Context of the organization

ISO 9001:2015 (4.1)

- The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.

- The organization shall monitor and review information about these external and internal issues.

ISO 14001:2015 (4.1)

- The organization shall determine external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended outcomes of its environmental management system. Such issues shall include environmental conditions being affected by or capable of affecting the organization.

4 Context of the organization

ISO 9001:2015 (4.2)

Understanding the needs and expectations of interested parties

Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:

a) the interested parties that are relevant to the quality management system;

b) the requirements of these interested parties that are relevant to the quality management system.

The organization shall monitor and review information about these interested parties and their relevant requirements.

ISO 14001:2015 (4.2)

Understanding the needs and expectations of interested parties

The organization shall determine:

a) the interested parties that are relevant to the environmental management system;

b) the relevant needs and expectations (i.e. requirements) of these interested parties;

c) which of these needs and expectations become its compliance obligations.

4 Context of the organization

ISO 9001:2015 (4.3)

- ………………………
- The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system.
- Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

ISO 14001:2015 (4.3)

- Once the scope is defined, all activities, products and services of the organization within that scope need to be included in the environmental management system.
- The scope shall be maintained as documented information and be available to interested parties.

4 Context of the organization

ISO 9001:2015 (4.4)

4.4 Quality management system and its processes

4.4.1 establish, implement, maintain and continually improve QMS including the processes needed and their interactions,

The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall…….*(similar to 4.1 of the previous standard with risks and opportunities added)*

4.4.2 To the extent necessary, the organization shall….. *(Similar to 4.2.1 of the previous standard)*

ISO 14001:2015 (4.4)

4.4 Environmental management system

establish, implement, maintain and continually improve an EMS, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

5 Leadership

ISO 9001:2015 (5.1)

- 5.1.1 Top Management shall demonstrate leadership and commitment ….. (identical text)

- d) promoting the use of the process approach and risk-based thinking;

- 5.1.2 Customer focus

ISO 14001:2015 (5.1)

- Identical text to 5.1 except sub-section d)

- (customer focus is not addressed)

5 Leadership

ISO 9001:2015 (5.2)

Policy

- Similar text
- Documented
- Communicated

ISO 14001:2015 (5.2)

Policy

- Similar text
- Documented
- Communicated

5 Leadership

ISO 9001:2015 (5.3)

Organizational roles, responsibilities and authorities

- Similar text
- *(Addition)* b) ensuring that the processes are delivering their intended outputs;
- *(Addition)* d) ensuring the promotion of customer focus throughout the organization;
- *(Addition)* e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

ISO 14001:2015 (5.3)

Organizational roles, responsibilities and authorities

- Similar text

- Process accountability, Customer focus, change management not addressed

6 Planning

ISO 9001:2015 (6.1)

Actions to address risks and opportunities

- QMS Assurance
- Preventive actions
- Improvements
- Risks and opportunities.

ISO 14001:2015 (6.1)

Actions to address risks and opportunities

- Environmental aspects
- Compliance obligations
- Prevention of pollution
- Continual improvement
- Determination of potential emergency
- Aspect impact assessment
- Methodology
- Documentation (aspect/impact, compliance)
- Planning action based on significance

6 Planning

ISO 9001:2015 (6.2)

Quality objectives and planning to achieve them

- Similar text
- Quality objectives
- Documentation
- SMART approach (What, resources, who, when, how)

ISO 14001:2015 (6.2)

Environmental objectives and planning to achieve them

- Similar text
- Environmental objectives
- Documentation
- SMART approach (What, resources, who, when, how)
- Integration with business processes

6 Planning

ISO 9001:2015 (6.3)

Planning for changes

- Purpose and potential consequences;

- Integrity of QMS

- Availability of resources

- Allocation/reallocation of responsibilities

ISO 14001:2015

Not addressed

7 Support

ISO 9001:2015 (7.1.1)

Resources - General

- Common text

(Additional text)

- The organization shall consider:

    a) the capabilities of, and constraints on, existing internal resources;

    b) what needs to be obtained from external providers.

ISO 14001:2015 (7.1)

Resources

- Common text

7 Support

ISO 9001:2015 (7.1.2)

Resources - People

- The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

ISO 14001:2015

Not separately addressed

7 Support

ISO 9001:2015 (7.1.3)

Resources - Infrastructure

- The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

ISO 14001:2015

Not separately addressed

7 Support

ISO 9001:2015 (7.1.4)

Resources – Environment for operation of processes

- The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services. .

ISO 14001:2015

Not separately addressed

7 Support

ISO 9001:2015 (7.1.5)

Resources – Monitoring and measuring resources

- The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

- Appropriate, maintained, calibration, actions on validity of measurements

- Documentation

- Measurement traceability

ISO 14001:2015

Addressed in Clause 9.1

7 Support

ISO 9001:2015 (7.1.6)

Resources – Organizational knowledge

- The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

- Maintenance, availability, updating

ISO 14001:2015

Not separately addressed

7 Support

ISO 9001:2015 (7.2)

Competence

- Similar text
- Documentation

ISO 14001:2015 (7.2)

Competence

- Similar text
- Training in environmental aspect and EMS
- Documentation

7 Support

ISO 9001:2015 (7.3)

Awareness

- Similar text
- Policy, objectives, effectiveness, benefits, implication of non-conformance

ISO 14001:2015 (7.3)

Awareness

- Similar text
- Policy, objectives, effectiveness, benefits, implication of non-conformance

7 Support

ISO 9001:2015 (7.4)

Communication

- Similar text (What, when, whom, how, who)

ISO 14001:2015 (7.4)

Communication

- Similar text (What, when, whom, how, who)

(Additional)

- Compliance obligations, EMS information, response to communication,
- Documentation
- Internal communication
- External communication

7 Support

ISO 9001:2015 (7.5)

Documented information

7.5.1 General

- Identical text

7.5.2 Creating and updating

- Identical text

7.5.3 Control of documented information

- Identical text

(Additional)

- Documented information retained as evidence of conformity shall be protected from unintended alterations.

ISO 14001:2015 (7.5)

Documented information

7.5.1 General

- Identical text

7.5.2 Creating and updating

- Identical text

7.5.3 Control of documented information

- Identical text

8 Operation

ISO 9001:2015 (8.1)

Operation Planning and control *(Similar to 7.1 of the previous standard)*

- Aligned to products and services;
- Processes related to meet requirements of products and services;
- Criteria for acceptance, conformity, resource determination;
- Documentation adequacy.

ISO 14001:2015 (8.1)

Operation Planning and control

- Aligned to EMS;
- Operating criteria;
- Change management;
- Control of outsourced processes;
- Life cycle perspective;
- Documentation adequacy.

8 Operation

ISO 9001:2015 (8.2.1)

Interactions with customers and interested parties *(Similar to 7.2 of the previous standard)*

8.2.1 Customer communication

- Customer communication (product and service information, handling enquiries, orders and changes, customer feedback and complaints, customer property, contingency actions)
- Processes related to meet requirements of products and services;
- Criteria for acceptance, conformity, resource determination;
- Documentation adequacy.

ISO 14001:2015 (8.2)

Emergency preparedness and response

- Plan and prepare;
- Respond to actual emergency;
- Prevent or mitigate consequences;
- Periodic tests and review;
- Training;
- Documentation.

8 Operation

ISO 9001:2015 (8.2.3)

Review of requirements related to the product *(Similar to 7.2.2 of the previous standard)*

Review of ability to meet the requirements

- Requirements specified by customer, delivery, post-delivery
- Requirements not stated by the customer, but necessary
- Requirement specified by the organization
- Applicable statutory and regulatory;
- Changes in contract or order requirements;
- Conformation of requirement.
- Documentation.

ISO 14001:2015

(Not addressed)

8 Operation

ISO 9001:2015 (8.2.4)

Changes to requirements for products and services *(Similar to 7.2.2 of the previous standard)*

- The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed

ISO 14001:2015

(Not addressed)

8 Operation

ISO 9001:2015 (8.3)

Design and development of products and services *(Similar to 7.3 of the previous standard)*

- 8.3.1 General
- 8.3.2 Design and development planning
- 8.3.3 Design and development inputs
- 8.3.4 Design and development controls
- 8.3.5 Design and development outputs
- 8.3.6 Design and development changes

ISO 14001:2015

(Not addressed)

8 Operation

ISO 9001:2015 (8.4)

Control of externally provided processes, products and services *(Similar to 7.4 of the previous standard)*

8.4.1 General

- For incorporation, direct supply or process provision;
- Criteria for evaluation, selection, monitoring of performance and reevaluation;
- Documentation

8.4.2 Type and extent of control

- Define the controls;
- Effectiveness of the controls
- Verification and other activities.

8.4.3 Information for external providers

ISO 14001:2015

(Addressed in 8.1)

8 Operation

ISO 9001:2015 (8.5)

Product and service provision

8.5.1 Control of production and service provision *(Similar to 7.5.1 of the previous standard)*

8.5.2 Identification and traceability *(Similar to 7.5.3 of the previous standard)*

8.5.3 Property belonging to customers or external parties*(Similar to 7.5.4 of the previous standard)*

8.5.4 Preservation *(Similar to 7.5.5 of the previous standard*

8.5.5 Post delivery activities

- The organization shall meet requirements for post-delivery activities associated with the products and services.

- Statutory and regulatory requirement, potential undesired consequences, nature_use_intended lifetime, customer requirements, customer feedback.

8.5.6 Control of changes

- Review and control changes for production or service provision;

- Documentation of changes

ISO 14001:2015

(Not addressed)

8 Operation

ISO 9001:2015 (8.6)

Release of products and services

The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

Documentation

ISO 14001:2015

(Not addressed)

8 Operation

ISO 9001:2015 (8.7)

Control of nonconforming outputs

- *(Similar to 8.3 of the previous standard)*

- The organization shall deal with nonconforming outputs in one or more of the following ways:

  a) correction;

  b) segregation, containment, return or suspension of provision of products and services;

  c) informing the customer;

  d) obtaining authorization for acceptance under concession.

- Conformity to the requirements shall be verified when nonconforming outputs are corrected.

- Documentation

ISO 14001:2015

(Not addressed)

9 Performance evaluation

ISO 9001:2015 (9.1)

Monitoring, measurement, analysis and evaluation

9.1.1 General

- Similar text

9.1.2 Customer satisfaction

- Perception measurements
- Determine methods of obtaining, monitoring and reviewing

9.1.3 Analysis and evaluation

- The organization shall analyze and evaluate appropriate data and information arising from monitoring and measurement.

ISO 14001:2015 (9.1)

Monitoring, measurement, analysis and evaluation

9.1.1 General

- Similar text

(Addition)

- Use of calibrated equipment
- Environmental performance evaluation
- Internal/external communication of environmental performance
- Documentation

9.1.2 Evaluation of compliance

- Compliance obligations
- Documentation

9 Performance evaluation

ISO 9001:2015 (9.2)

Internal Audit

9.2.1 General

- Similar text

9.2.2 Internal audit programme

- Similar text

Documentation.

ISO 14001:2015 (9.2)

Internal Audit

9.2.1 General

- Similar text

9.2.2 Internal audit programme

- Similar text

Documentation.

9 Performance evaluation

ISO 9001:2015 (9.3)

Management Review

- **Similar text**

- **Documentation**

ISO 14001:2015 (9.3)

Management review

- **Similar text**

- **Documentation**

10 Improvement

ISO 9001:2015

10.1 General

- Similar text

10.2 General

- Similar text

(Addition)

e) update risks and opportunities determined during planning, if necessary;

- Documentation

10.1 Continual improvement

- **Similar text**

ISO 14001:2015

10.1 General

- Similar text

10.2 General

- Similar text

- Documentation

10.1 Continual improvement

- **Similar text**

MOVING FORWARD IN LMS

This section will cover

- JAS-ANZ transition plan.

- LMS transition plan.

- Availability of LMS certificates.

DAC Transition Plan

- **2. TRANSITION**
- The International Accreditation Forum (IAF) and the ISO Committee on Conformity Assessment (CASCO) have agreed to a **three year transition period** from the publication date of ISO 9001:2015.
- IAF Resolution 2013-15 was passed by the IAF General Assembly in Seoul on 23 October 2013 endorsing a 3 year transition period to ISO 9001:2015.
- **2.1 Validity of certifications to ISO 9001:2008**
- ISO 9001:2008 certifications will not be valid after three years from publication of ISO 9001:2015.
- The expiry date of certifications to ISO 9001:2008 issued during the transition period needs to correspond to the end of the three year transition period.

DAC Transition

- **3. SPECIFIC GUIDANCE FOR INTERESTED PARTIES INVOLVED IN CERTIFICATION AND ACCREDITATION**
- For any organisation the degree of change necessary will be dependent upon the maturity and effectiveness of the current management system, organisational structure and practices, therefore an impact analysis/gap assessment is strongly recommended in order to identify realistic resource and time implications.

- **3.1 Organizations using ISO 9001:2008**
- Organizations using ISO 9001:2008 are recommended to take the following actions:
- i) Identify organizational gaps which need to be addressed to meet new requirements.
- ii) Develop an implementation plan.
- iii) Provide appropriate training and awareness for all parties that have an impact on the effectiveness of the organisation.
- iv) Update the existing quality management system (QMS) to meet the revised requirements and provide verification of effectiveness.
- v) Where applicable, liaise with their Certification Body for transition arrangements.

LMS Transition Plan

- LMS will:-
- i) Train their auditors and verify the results to ensure the relevant level of competence is demonstrated.
- ii) Communicate with existing clients and share guidance on the transition process and arrangements for transition.
- iii) Plan the timing of audit and certification activities for the revised standard.
- iv) Consider the stated transition period and current certification period.
- v) Plan the timing of certification decisions for upgrading certification documents.
- vi) Encourage current users of ISO 9001:2008 to implement ISO 9001:2015 at an early stage,
- Vii) Encourage new users to implement ISO 9001:2015.
- Viii) Arrange audit schedules for existing client organizations.

LMS Transition Plan

- LMS will Submit requirements to DAC in December 2015, after which subject to DAC approval existing clients can be upgrades either at their normal surveillance visit or with a special visit if requested but before mid 2018

LMS Certificates

- ISO9001:2008 certificates will no longer be issued after our accreditation to ISO9001 and 14001:2015.

- ISO9001:2008 or 14001:2004 certificates will no longer be valid after September 2018