

# Integrated Management Systems Awareness Training

ISO 9001:2015, ISO 14001:2015  
and ISO 45001:2018

QUALITY



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# Course Objectives

- Provide sufficient knowledge and understanding of the various clauses and requirements of the ISO 9001:2015, ISO 14001:2015 and ISO 45001: 2018 standards.
- Provide basic guidance for the planning, preparation and delivery of an Integrated Management System audit.

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# Contents

## **ISO 9001:2015/ISO 14001:2015/ISO 45001: 2018 Auditor Training**

Chapter 1 – The ISO Standards Explained

Chapter 2 – Basic Principles and Methodologies

Chapter 3 – ISO 9001:2015, ISO 14001:2015 and ISO 45001: 2018 Requirements

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# A BRIEF INTRODUCTION TO OMNEX

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# Omnex Introduction

- International consulting, training and software development organization founded in 1985.
- Specialties:
  - Integrated management system solutions.
  - Elevating the performance of client organizations.
  - Consulting and training services in:
    - Quality Management Systems, e.g., ISO 9001, ISO/TS 16949, AS9100, QOS
    - Environmental Management Systems, e.g., ISO 14001
    - Health and Safety Management Systems, e.g., OHSAS 18001
- Leader in Lean, Six Sigma and other breakthrough systems and performance enhancement.
  - Provider of Lean Six Sigma services to Automotive Industry via AIAG alliance.





# About Omnex

- Headquartered in Ann Arbor, Michigan with offices in major global markets.
- In 1995-97 provided global roll out supplier training and development for Ford Motor Company.
- Trained more than 100,000 individuals in over 30 countries.
- Workforce of over 400 professionals, speaking over a dozen languages.
- Former Delegation Leader of the International Automotive Task Force (IATF) responsible for ISO/TS16949.
- Served on committees that wrote QOS, ISO 9001:2000, QS-9000 and its Semiconductor Supplement, and ISO IWA 1 (ISO 9000 for healthcare).
- Member of AIAG manual writing committees for FMEA, SPC, MSA, Sub-tier Supplier Development, Error Proofing, and Effective Problem Solving (EPS).





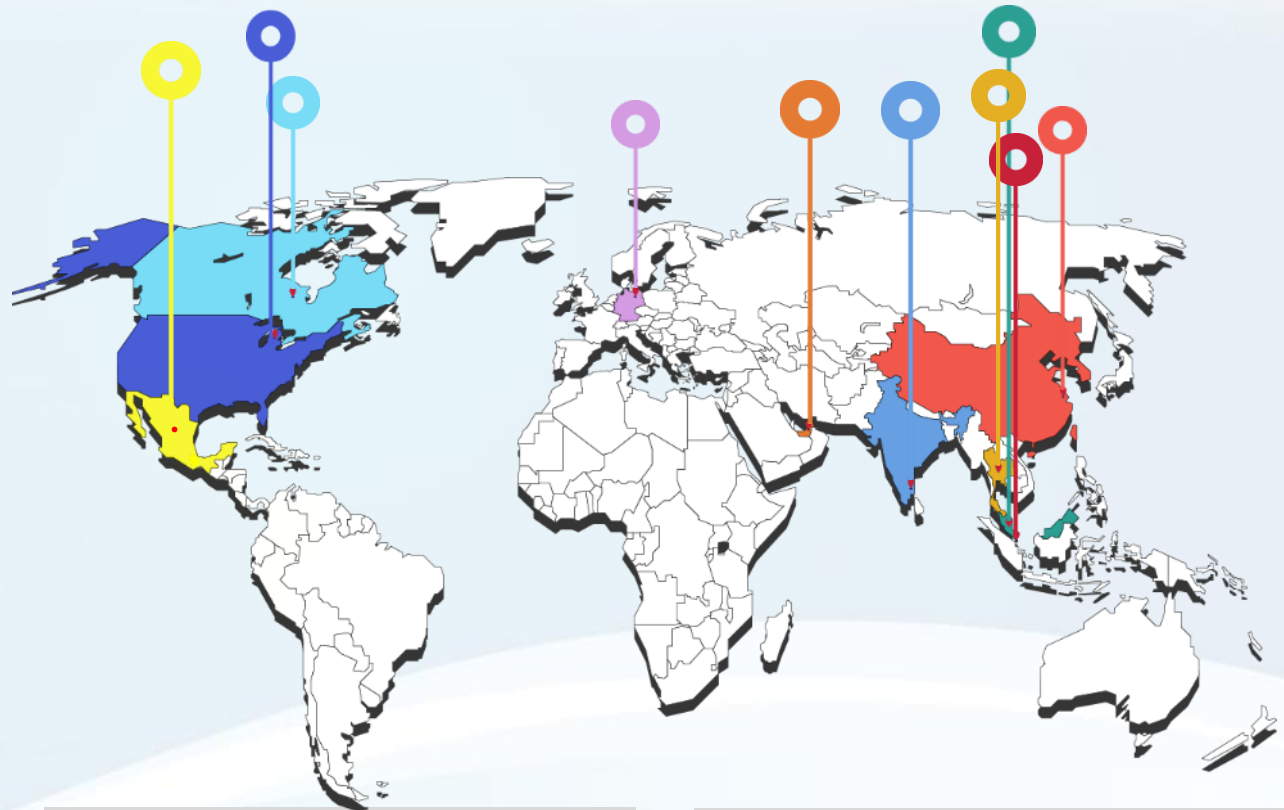
# Omnex Worldwide Offices



Omnex is headquartered and operates from the United States through offices in Michigan.

The company maintains international operations in many countries to provide comprehensive services to clients throughout Western Europe, Latin America and the Pacific Rim.

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West Coast Operations (San Jose, CA)

● Asia Pacific HQ (Chennai, Pune, Delhi, Bangalore)

● China (Shanghai, Guangzhou, Wuhan, Chengdu)

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● Europe (Berlin, Germany)

● Middle East (Dubai, Saudi Arabia, Bahrain)

● Thailand (Bangkok)

● Mexico (Monterrey)

● Singapore

● Malaysia (Kuala Lumpur)



# Rules of the Classroom

- ✓ Start and end on time
- ✓ Return from breaks and lunch on time
- ✓ All questions welcome
- ✓ Your input is valuable and is encouraged OMNEX
- ✓ Don't interrupt others
- ✓ One meeting at a time
- ✓ Listen – and respect others' ideas
- ✓ No “buts” – keep an open mind
- ✓ Cell phones & pagers off or silent mode
- ✓ No e-mails, texting or tweeting during class
- ✓ If you must take a phone call or answer a text please leave the room for as short a period as possible

# Icebreaker

- Instructor Information:
  - Name
  - Background
- Student Introductions:
  - Name
  - Position / Responsibilities
  - What is your involvement in the Integrated Management System?
  - Please share something unique and/or interesting about yourself.



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# Chapter 1

## ISO 9001, ISO 14001 and ISO 45001 Standards Explained

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# Chapter 1: The Standards Explained— What We Will Cover

## Learning Objectives

At the end of this chapter, you will be able to:

- Describe the separate standards that make up an integrated management system
- Define the key terms in an integrated management system

## Chapter Agenda

- ISO 9001, ISO 14001 and ISO/DIS 45001 Series of Management System Documents
- Terminology and Definitions

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# ISO 9001, ISO 14001 AND ISO 45001 SERIES OF MANAGEMENT SYSTEM DOCUMENTS



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# ISO 9000, ISO 14001 and OHSAS 18001 Management System Documents

ISO 9001:2015	ISO 14004:2015	ISO 45001: 2018
<b>ISO 9001</b> ISO 9001 QMS Requirements	<b>ISO 14001</b> ISO 14001 EMS Requirements with Guidance for Use	<b>ISO 45001</b> ISO 45001 OHS Requirements with Guidance for Use
<b>ISO 9000</b> ISO 9000 QMS Fundamentals and Vocabulary	<b>ISO 14004</b> ISO 14004 EMS Guidelines on Implementation	
<b>ISO 9004</b> ISO 9004 Guidance for Improvement	<b>ISO 14050</b> ISO 14050 EMS Vocabulary	



# ISO 9001:2015 Clauses

## 1. Scope

## 2. Normative References

## 3. Terms and Definitions

## 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 QMS

4.4 QMS and its Processes

## 5. Leadership

5.1 Leadership and Commitment

5.1.2 Customer Focus

5.2 Policy

5.2.1 Establishing the Quality Policy

5.2.2 Communicating the Quality Policy

5.3 Organizational Roles, Responsibilities and Authorities

## 6. Planning

6.1 Actions to Address Risks and Opportunities

6.2 Quality Objectives and Planning to Achieve Them

6.3 Planning of Changes

## 7. Support

7.1 Resources

7.1.2 People

7.1.3 Infrastructure

7.1.4 Environment for the Operation of Processes

7.1.5 Monitoring and Measuring Resources

7.1.6 Organizational Knowledge

7.2 Competence

7.3 Awareness

7.4 Communication

7.5 Documented Information

7.5.2 Creating and Updating

7.5.3 Control of Documented Information

# ISO 9001:2015 Clauses

## 8. Operation

- 8.1 Operational Planning and Control
- 8.2 Requirements for Products and Services
  - 8.2.1 Customer Communication
  - 8.2.2 Determining the Requirements for Products and Services
  - 8.2.3 Review of Requirements for Products and Services
  - 8.2.4 Changes to Requirements for Products and Services
- 8.3 Design and Development of Products and Services
  - 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
- 8.4 Control of Externally Provided Processes, Products and Services
  - 8.4.2 Type and Extent of Control
  - 8.4.3 Information for External Providers

## 8. Operation (cont'd)

- 8.5 Production and Service Provision
  - 8.5.1 Control of Production and Service Provision
  - 8.5.2 Identification and Traceability
  - 8.5.3 Property Belonging to Customers or External Providers
  - 8.5.4 Preservation
  - 8.5.5 Post-delivery Activities
  - 8.5.6 Control of Changes
- 8.6 Release of Products and Services
- 8.7 Control of Nonconforming Outputs

## 9. Performance Evaluation

- 9.1 Monitoring, Measurement, Analysis and Evaluation
  - 9.1.2 Customer Satisfaction
  - 9.1.3 Analysis and Evaluation
- 9.2 Internal Audit
- 9.3 Management Review
  - 9.3.2 Management Review Inputs
  - 9.3.3 Management Review Outputs

## 10. Improvement

- 10.2 Nonconformity and Corrective Action
- 10.3 Continual Improvement

# ISO 14001:2015 Clauses

- 1. Scope**
- 2. Normative References**
- 3. Terms and Definitions**
- 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 EMS
  - 4.4 Environmental Management System
- 5. Leadership**
  - 5.1 Leadership and Commitment
  - 5.2 Environmental Policy
  - 5.3 Organizational Roles, Responsibilities and Authorities
- 6. Planning**
  - 6.1 Actions to Address Risks and Opportunities
    - 6.1.2 Environmental Aspects
    - 6.1.3 Compliance Obligations
    - 6.1.4 Planning Action
  - 6.2 Environmental Objectives and Planning to Achieve Them
    - 6.2.1 Environmental Objectives
    - 6.2.2 Planning Actions to Achieve Environmental Objectives

# ISO 14001:2015 Clauses

## 7. Support

- 7.1 Resources
- 7.2 Competence
- 7.3 Awareness
- 7.4 Communication
  - 7.4.2 Internal Communication
  - 7.4.3 External Communication
- 7.5 Documented Information
  - 7.5.2 Creating and Updating
  - 7.5.3 Control of Documented Information

## 8. Operation

- 8.1 Operational Planning & Control
- 8.2 Emergency Preparedness and Response

## 9. Performance Evaluation

- 9.1 Monitoring, Measurement, Analysis and Evaluation
  - 9.1.2 Evaluation of Compliance
- 9.2 Internal Audit
  - 9.2.2 Internal Audit Program
- 9.3 Management Review

## 10. Improvement

- 10.2 Nonconformity and Corrective Action
- 10.3 Continual Improvement

# ISO 45001 Clauses

## 1. Scope

## 2. Normative References

## 3. Terms and Definitions

## 4. Context of the Organization . o.m.n.ex

4.1 Understanding the organization and its context

4.2 Understanding the needs and expectations of workers and other interested parties

4.3 Determining the scope of the OH&S MS

4.4 OH&S management system

## 5. Leadership and Worker Participation

5.1 Leadership and commitment

5.2 OH&S policy

5.3 Organizational roles, responsibilities and authorities

5.4 Consultation and participation of workers

## 6. Planning

### 6.1 Actions to address risks and opportunities

– 6.1.1 General

– 6.1.2 Hazard identification and assessment of risks and opportunities

– 6.1.3 Determination of legal requirements and other requirements

– 6.1.4 Planning action

### 6.2 OH&S objectives and planning to achieve them

– 6.2.1 OH&S objectives

– 6.2.2 Planning to achieve OH&S objectives

## 7. Support

7.1 Resources

7.2 Competence

7.3 Awareness

7.4 Communication

– 7.4.1 General

– 7.4.2 Internal communication

– 7.4.3 External communication

# ISO 45001: 2018 Clauses

## 7. Support

- 7.5 Documented information
  - 7.5.1 General
  - 7.5.2 Creating and updating
  - 7.5.3 Control of documented Information

## 8. Operation

- 8.1 Operational planning and control
  - 8.1.1 General
  - 8.1.2 Eliminating hazards and reducing  
OH&S risks
  - 8.1.3 Management of change
  - 8.1.4 Procurement
- 8.2 Emergency preparedness and response

## 9. Performance evaluation

- 9.1 Monitoring, measurement, analysis and  
performance evaluation
  - 9.1.1 General
  - 9.1.2 Evaluation of compliance
- 9.2 Internal audit
  - 9.2.1 General
  - 9.2.2 Internal audit programme
- 9.3 Management review

## 10. Improvement

- 10.1 General
- 10.2 Incident, nonconformity and corrective  
action
- 10.3 Continual improvement

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# IMS Relative Clauses

<b>ISO 9001:2015</b>	<b>ISO 14004:2015</b>	<b>ISO 45001</b>
4.1 Understanding the Organization and its Context	4.1 Understanding the Organization and its Context	4.1 Understanding the organization and its context
4.2 Understanding the Needs and Expectations of Interested Parties	4.2 Understanding the Needs and Expectations of Interested Parties	4.2 Understanding the needs and expectations of workers and other interested parties
4.3 Determining the Scope of the QMS	4.3 Determining the Scope of the EMS	4.3 Determining the scope of the OH&S management system
4.4 Quality Management System and its Processes	4.4 Environmental Management System	4.4 OH&S management system



# IMS Relative Clauses

ISO 9001:2015	ISO 14004:2015	ISO 45001: 2018
<p><b>5. Leadership and Commitment</b>                      5.1 Leadership and Commitment                      5.1.1 General                      5.1.2 Customer focus</p>	<p><b>5. Leadership and Commitment</b>                      5.1 Leadership and Commitment</p>	<p><b>5. Leadership and worker participation</b>                      5.1 Leadership and commitment</p>
<p>5.2 Policy                      5.2.1 Establishing quality policy                      5.2.2 Communicating quality policy</p>	<p>5.2 Environmental Policy</p>	<p>5.2 OH&amp;S policy</p>
<p>5.3 Organizational Roles, Responsibilities and Authorities</p>	<p>5.3 Organizational Roles, Responsibilities and Authorities</p>	<p>5.3 Organizational roles, responsibilities and authorities</p>
<p><b>NO EQUIVALENT REQUIREMENT</b></p>	<p><b>NO EQUIVALENT REQUIREMENT</b></p>	<p>5.4 Consultation and participation of workers</p>

# IMS Relative Clauses

ISO 9001:2015	ISO 14004:2015	ISO 45001: 2018
<b>6. Planning</b>	<b>6. Planning</b>	<b>6. Planning</b>
6.1 Actions to Address Risks and Opportunities	6.1 Actions to Address Risks and Opportunities 6.1.1 General 6.1.2 Environmental Aspects 6.1.3 Compliance Obligations 6.1.4 Planning Action	6.1 Actions to address risks and opportunities 6.1.1 General 6.1.2 Hazard identification and assessment of risks and opportunities 6.1.3 Determination of legal requirements and other requirements 6.1.4 Planning action
6.2 Quality Objectives and Planning to Achieve Them	6.2 Environmental Objectives and Planning to Achieve Them 6.2.1 Environmental Objectives 6.2.2 Planning Actions to Achieve Environmental Objectives	6.2 OH&S objectives and planning to achieve them 6.2.1 OH&S objectives 6.2.2 Planning to achieve OH&S objectives
6.3 Planning of Changes	<b>NO EQUIVALENT REQUIREMENT</b>	<b>NO EQUIVALENT REQUIREMENT</b>

# IMS Relative Clauses

ISO 9001:2015	ISO 14004:2015	ISO 45001: 2018
<b>7. Support</b>	<b>7. Support</b>	<b>7. Support</b>
7.1 Resources 7.1.1 General 7.1.2 People 7.1.3 Infrastructure 7.1.4 Environment for the operation of processes 7.1.5 Monitoring and measuring resources 7.1.6 Organizational knowledge	7.1 Resources  <b>NO EQUIVALENT SUB CLAUSES</b>	7.1 Resources  <b>NO EQUIVALENT SUB CLAUSES</b>
7.2 Competence	7.2 Competence	7.2 Competence
7.3 Awareness	7.3 Awareness	7.3 Awareness
7.4 Communication	7.4 Communication 7.4.1 General 7.4.2 Internal Communication 7.4.3 External Communication	7.4 Communication
<b>7.5 Documented Information</b> 7.5.1 General 7.5.2 Creating and updating 7.5.3 Control of documented Information	<b>7.5 Documented Information</b> 7.5.1 General 7.5.2 Creating and updating 7.5.3 Control of documented Information	<b>7.5 Documented Information</b> 7.5.1 General 7.5.2 Creating and updating 7.5.3 Control of documented Information

# IMS Relative Clauses

ISO 9001:2015	ISO 14004:2015	ISO 45001: 2018
8.1 Operational Planning and Control	8.1 Operational Planning and Control	8.1 Operational planning and control 8.1.1 General 8.1.2 Eliminating hazards and reducing OH&S risks 8.1.3 Management of change
8.2 Requirements for Products and Services	No ISO 14001:2015 Equivalent	No ISO 45001: 2018 Equivalent
No ISO 9001:2015 Equivalent	8.2 Emergency Preparedness & Response	8.2 Emergency preparedness and response
8.3 Design and Development of Products and Services	No ISO 14001:2015 Equivalent	No ISO 45001: 2018 Equivalent

# IMS Relative Clauses

ISO 9001:2015	ISO 14004:2015	ISO 45001: 2018
8.4 Control of Externally Provided Processes, Products and Services 8.4.1 General 8.4.2 Type and extent of control 8.4.3 Information for external providers	<b>No ISO 14001:2015 Equivalent</b>	8.1.4 Procurement
8.5 Production and Service Provision	<b>No ISO 14001:2015 Equivalent</b>	<b>No ISO 45001: 2018 Equivalent</b>
8.6 Release of Products and Services	<b>No ISO 14001:2015 Equivalent</b>	<b>No ISO 45001: 2018 Equivalent</b>
8.7 Control of Nonconforming Outputs	<b>No ISO 14001:2015 Equivalent</b>	<b>No ISO 45001: 2018 Equivalent</b>

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# IMS Relative Clauses

<b>ISO 9001:2015</b>	<b>ISO 14004:2015</b>	<b>ISO 45001: 2018</b>
9.1 Monitoring, Measurement, Analysis and Evaluation	9.1 Monitoring, Measurement, Analysis and Evaluation 9.1.1 General 9.1.2 Evaluation of compliance	9.1 Monitoring, Measurement, Analysis and Evaluation 9.1.1 General 9.1.2 Evaluation of compliance
9.2 Internal Audit 9.2.1 General 9.2.2 Internal audit program	9.2 Internal Audit 9.2.1 General 9.2.2 Internal audit program	9.2 Internal audit 9.2.1 General 9.2.2 Internal audit program
9.3 Management Review 9.3.1 General 9.3.2 Management review inputs. 9.3.3 Management review outputs	9.3 Management Review	9.3 Management review
<b>ISO 9001:2015</b>	<b>ISO 14004:2015</b>	<b>ISO 45001: 2018</b>
10.1 (Improvement) General	10.1 (Improvement) General	10.1 (Improvement) General
10.2 Nonconformity and Corrective Action	10.2 Nonconformity and Corrective Action	10.2 Incident, Nonconformity and Corrective Action
10.3 Continual Improvement	10.3 Continual Improvement	10.3 Continual Improvement



# Selected Core Terminology

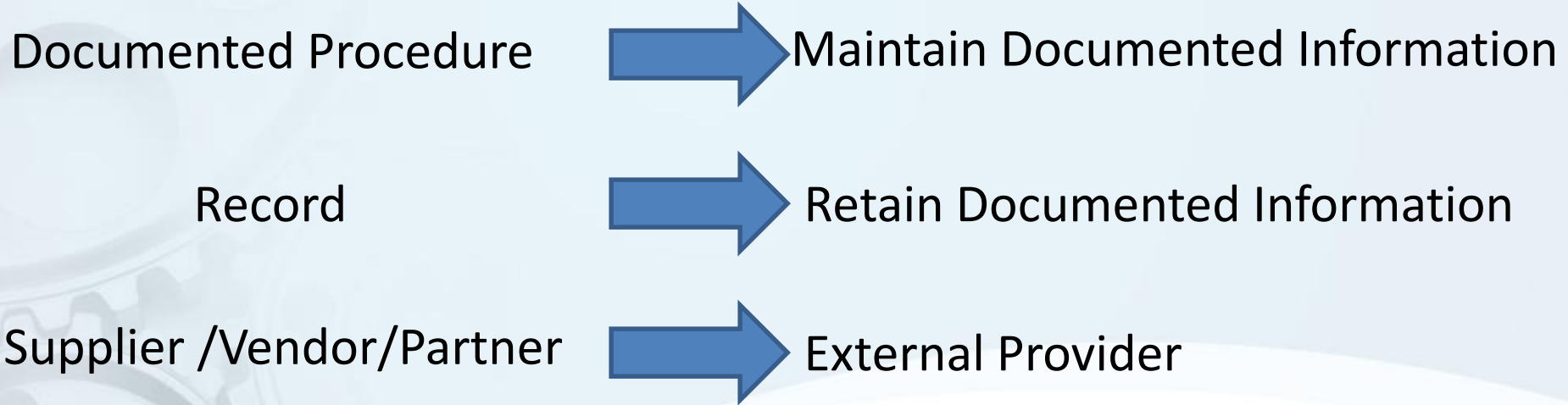
ISO 9001:2015	ISO 14004:2015	ISO 45001: 2018
<p><b>Revised Definitions</b></p> <ul style="list-style-type: none"> <li>• Organization</li> <li>• Interested Party</li> <li>• Quality Management System</li> <li>• Objective</li> <li>• Competence</li> <li>• Corrective Action</li> <li>• Continual Improvement</li> </ul>	<p><b>Revised Definitions</b></p> <ul style="list-style-type: none"> <li>• Organization</li> <li>• Environmental Policy</li> <li>• Interested Party</li> <li>• Management System</li> <li>• Objective</li> <li>• Competence</li> <li>• Corrective Action</li> <li>• Continual Improvement</li> <li>• Applicable</li> <li>• Appropriate</li> </ul>	<p><b>OH&amp;S Specific</b></p> <ul style="list-style-type: none"> <li>• Acceptable Risk</li> <li>• Hazard</li> <li>• Hazard Identification</li> <li>• Injury &amp; Ill Health</li> <li>• Incident</li> <li>• OH&amp;S Mgmt. System</li> <li>• OH&amp;S Opportunity</li> <li>• Risk</li> <li>• Risk Assessment</li> <li>• Work Place</li> <li>• Worker</li> <li>• Participation</li> <li>• Consultation</li> <li>• Workplace</li> <li>• Contractor</li> </ul>



# Selected Core Terminology

ISO 9001:2015	ISO 14004:2015	ISO 45001: 2018
<p><b>New Definitions</b></p> <ul style="list-style-type: none"> <li>• Risk</li> <li>• Documented Information</li> <li>• Performance</li> <li>• Context of the Organization</li> <li>• Monitoring</li> <li>• Improvement</li> <li>• Knowledge</li> </ul>	<p><b>New Definitions</b></p> <ul style="list-style-type: none"> <li>• Risk</li> <li>• Env. Condition</li> <li>• Env. Performance</li> <li>• Compliance Obligation</li> <li>• Indicator</li> <li>• Documented Information</li> <li>• Context of the Organization</li> <li>• Monitoring</li> <li>• Intended Outcome</li> <li>• Life Cycle</li> <li>• Outsource</li> </ul>	<ul style="list-style-type: none"> <li>• Risk</li> <li>• Organization</li> <li>• Requirement</li> <li>• Policy</li> <li>• Interested party (preferred term) Stakeholder (admitted term)</li> <li>• Management System</li> <li>• Top Management</li> <li>• Effectiveness</li> <li>• Performance</li> <li>• Objective</li> <li>• Outsource</li> <li>• Monitoring &amp; Measurement</li> <li>• Documented Information</li> <li>• Continual Improvement</li> </ul>

# Changes in ISO Terminology



**Applicable to all ISO Standards**



# Key Definitions for IMS

- **Product:** output of an organization that can be produced without any transaction taking place between the organization and the customer.
  - Hardware is tangible and its amount is a countable characteristic.
  - Processed materials are tangible and their amount is a continuous characteristic.
    - Hardware and processed materials often are referred to as goods.
  - Software consists of information regardless of delivery medium.
- **Output:** result of a process.
- **Service:** output of an organization with at least one activity necessarily performed between the organization and the customer.

# Key Definitions for IMS

- **Provider or Supplier:** organization that provides a product or a service.
  - Can be internal or external to the organization.
- **Organization:** person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives.
- **Top Management:** person or group of people who directs and controls an organization at the highest level.
  - **Note:** If the scope of the management system covers only part of an organization, then Top Management refers to those who direct and control that part of the organization.

# Key Definitions for IMS

- **Management System:** set of interrelated or interacting elements of an organization to establish policies and objectives and processes to achieve those objectives.
  - **Note:** A management system can address a single discipline or several disciplines e.g., quality management, financial management or environmental management.
  - **Note:** The scope of a management system can include the whole of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations.

# Key Definitions for IMS

- **Context of the Organization:** combination of internal and external issues that can have an effect on an organization's approach to developing and achieving its objectives.
- **Customer:** person or organization that could or does receive a product or a service that is intended for or required by this person or organization.
  - A customer can be internal or external to the organization.
- **Requirement:** need or expectation that is stated, generally implied or obligatory.
  - Requirements can be generated by different interested parties or by the organization itself.
- **Objective:** result to be achieved.



# Key Definitions for IMS

- **Environmental Condition:** state or characteristic of the environment as determined at a certain point of time.
- **Environmental Performance:** performance related to the management of environmental aspects.
- **Conformity:** fulfillment of a requirement.
- **Compliance:** fulfillment of an “official” requirement.\*
- **Interested Party:** person or organization that can affect, be affected by, or perceive itself to be affected by a decision or activity.
  - **Note 1:** Interested parties can include person(s) and groups concerned with or affected by the environmental performance (3.13) of an organization.
  - **Note 2:** To “perceive itself to be affected” means the perception has been made known to the organization.
  - **Note 3:** Interested parties can include customers, communities, suppliers, regulators, nongovernment organizations, investors, employees.

\* If the *audit criteria* are selected from *regulatory requirements* the audit finding can be called compliance or non-compliance.



# Key Definitions for IMS

- **Life Cycle:** consecutive and interlinked stages of a product system, from raw material acquisition or generation from natural resources to end-of-life treatment.
  - **Note:** Life cycle includes activities, products, and services and may include procured goods and services, as well as end-of-life treatment of products and delivery of services, for example, design, manufacture, transport, packaging and end-use or disposal.
- **Outsource:** make an arrangement where an external organization performs part of an organization's function or process.
- **Indicator:** measurable representation of the condition or status of operations, management or conditions.

# Key Definitions for IMS

- **Risk:** effects of uncertainty.
  - **Note:** An effect is a deviation from the expected – positive or negative.
  - **Note:** Uncertainty is the state, even partially, of deficiency of information to, understanding or knowledge of, an event, its consequence, its likelihood.
  - **Note:** Risk is often characterized by reference to potential “events” and “consequences”, or a combination of both.
  - **Note:** Risk is often expressed in terms of a combination of consequences of an event (including change in circumstances) and the associated “likelihood” of occurrence.
- **Risks and Opportunities:** potential adverse effects (threats) and potential beneficial effects (opportunities).

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# Key Definitions for IMS

- **Risk:** combination of the likelihood of an occurrence of a hazardous event or exposure(s) and the severity of injury or ill health that can be caused by the event or exposure(s).
- **Work Place:** any physical location in which work related activities are performed under the control of the organization.
- **Incident:** work-related event(s) in which an injury or ill health (regardless of severity) or fatality occurred, or could have occurred.
- **Ill health:** identifiable, adverse physical or mental condition arising from and/or made worse by a work activity and/or work-related situation.
- **Hazard:** source, situation, or act with a potential for harm in terms of human injury or ill health, or a combination of these.

# Key Definitions for IMS

- **Nonconformity:** non-fulfillment of a requirement.
- **Corrective Action:** action to eliminate the cause(s) of a nonconformity or an incident and to prevent recurrence.
- **ContinualImprovement:**recurring activity to enhance performance. O-M-N-E-X

**See Glossary for more terms and definitions**

# Key Definitions for IMS – Clarifications

- **Continual** indicates duration that occurs over a period of time, but with intervals of interruption (unlike *continuous* which indicates duration without interruption). **Continual** is therefore the appropriate word to use in the context of improvement.
- The words '*appropriate*' and '*applicable*' are not interchangeable.
  - *Appropriate* means suitable (for, to) and implies some degree of freedom, while *applicable* means relevant or possible to apply and implies that if it can be done, it should be done.
- **Consider** means you can choose to not do anything to address the intent.
- The terms **interested party** and **stakeholder** are synonymous, as they both represent the same concept.
- The word **ensure** means the responsibility can be delegated, but not the accountability to make sure that it is performed.

# Key Definitions for IMS – Clarifications

- **Documented Information** replaces the nouns *documentation* and *record*. The standard now uses the phrases:
  - *“retain documented information as evidence of...”* to mean records
  - **maintain documented information** to mean documentation, other than records
- The term **determine** implies a discovery process that results in knowledge.
- The term **intended outcome** means what the organization intends to achieve by implementing its environmental management system, which includes:
  - Enhancement of environmental performance
  - Conformance to compliance obligations
  - Fulfillment of environmental objectives
- The phrase **compliance obligations** replaces the phrase *“legal requirements and other requirements”*.
- The use of the word **any** implies selection and choice.



# Key Definitions for IMS

## *Clarifications*

- The term **intended outcome** means what the organization intends to achieve by implementing its environmental management system, which includes:
  - Enhancement of environmental performance
  - Conformance to compliance obligations
  - Fulfillment of environmental objectives
- The phrase **compliance obligations** replaces the phrase “***legal requirements and other requirements***”.
- The use of the word **any** implies selection and choice.



# Chapter 1: The Standards Explained— What We Covered

## Learning Objectives

You should now be able to:

- Describe the separate standards that make up an integrated management system
- Define the key terms in an integrated management system

## Chapter Agenda

- ISO 9001, ISO 14001 and ISO 45001: 2018 Series of Management System Documents
- Terminology and Definitions

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# Chapter 2

## Basic Principles and Methodologies

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# Chapter 2: Basic Principles and Methodologies

## — What We Will Cover

### Learning Objectives

At the end of this chapter, you will be able to:

- Describe principles and methodologies of the individual standards

### Chapter Agenda

- Basic Principles and Methodologies

QUALITY



# Basic Principles and Methodologies



# IMS Basic Principles & Methodology

- **PLAN**

- Determine context of the organization
- Determine interested party needs and expectations
- Define the scope of the EMS
- Identify the environmental aspects
- Establish policy, objectives and required controls

- **DO**

- Implement the processes

- **CHECK**

- Measure, monitor, analyze and evaluate the performance of the EMS

- **ACT**

- Take action to improve the EMS

- **CONTINUAL IMPROVEMENT**

- Expansion
- Enrichment
- Upgrading



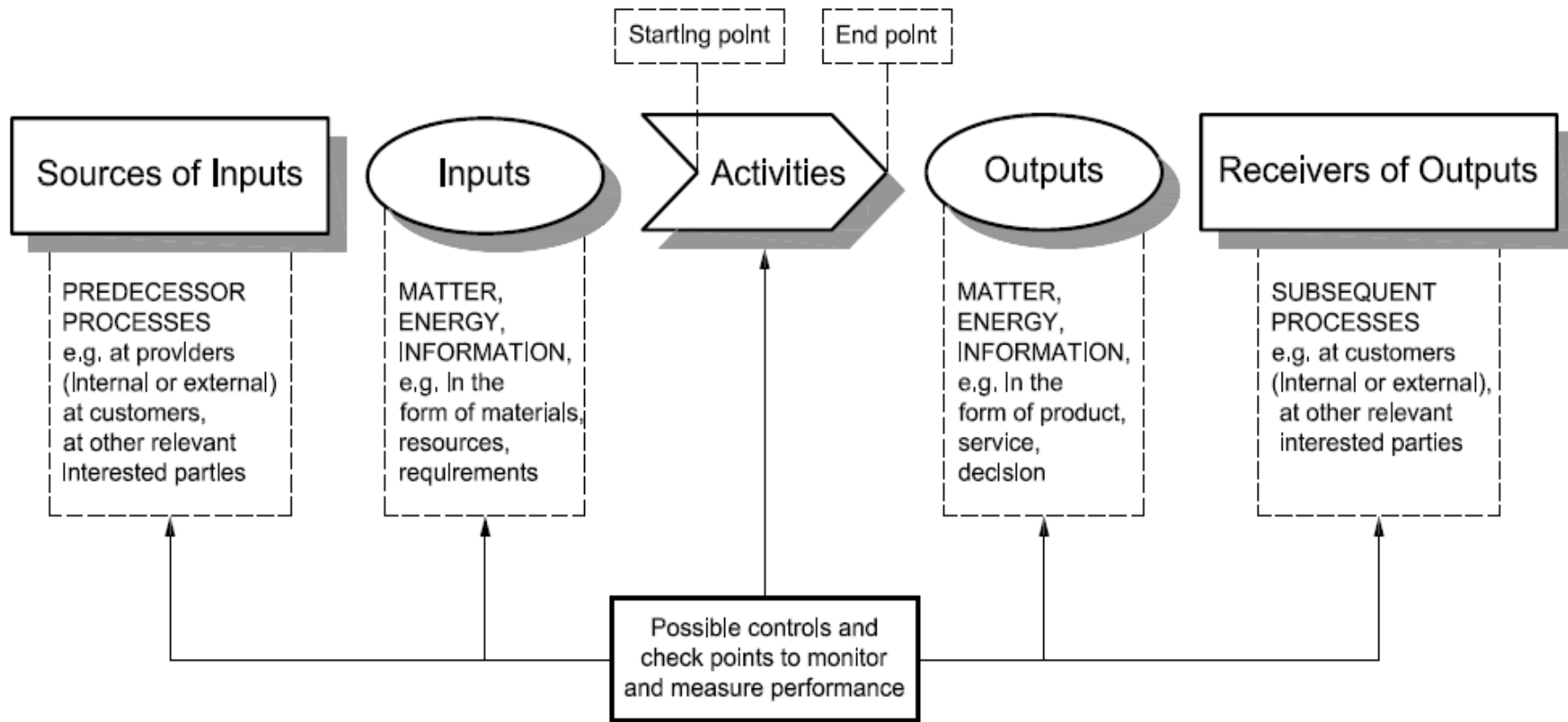
# IMS Principles & Methodology

## CONTINUAL IMPROVEMENT

- **Expand:** Cover more areas of the organization
- **Enrich:** Manage more activities, products, services, processes, resources, etc.
- **Upgrade:** Improvement of the framework of EMS
  - Structural
  - Organizational
- **Lessons Learned**

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# Process and Interactions (QMS and EMS)



source: ISO 9001:2015 and ISO 14001:2015



# The Process Approach

- ISO 9001, ISO 14001 and ISO 45001 promotes the adoption of a process approach when developing, implementing and improving management system effectiveness.
- Specific requirements considered essential to the adoption of a process approach are found in clause **4.4**.
- Understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its intended results.
- This approach enables the organization to control the interrelationships and interdependencies among the processes of the system, so that the overall performance of the organization can be enhanced.

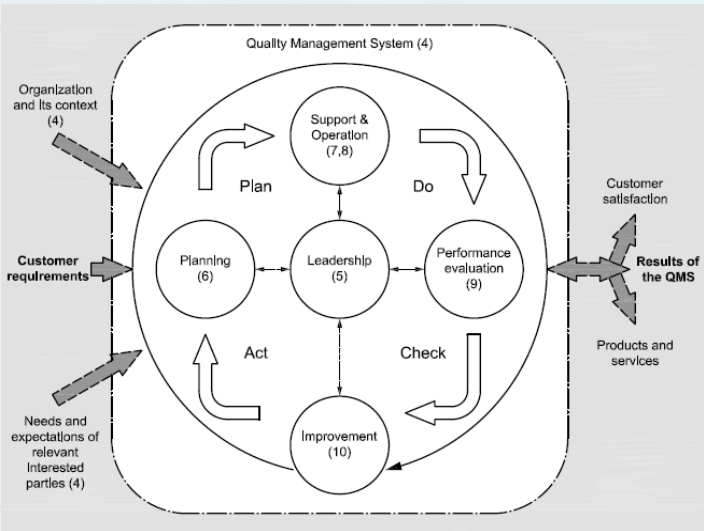
# The Process Approach

- Applies systematic definition, management of processes and their interactions to achieve the intended results aligned with the Quality Policy and strategic direction of the organization.
- Management of the processes and the system as a whole can be achieved using a “**Plan-Do-Check-Act**” (PDCA) methodology with an overall focus on *risk-based thinking* aimed at leveraging opportunities and preventing undesirable outcomes.
- Use of the process approach enables:
  - Understanding and meeting requirements
  - The consideration of processes in terms of what is “*value-added*”
  - The achievement of effective process performance
  - Improvement of processes based on evaluation of data and information

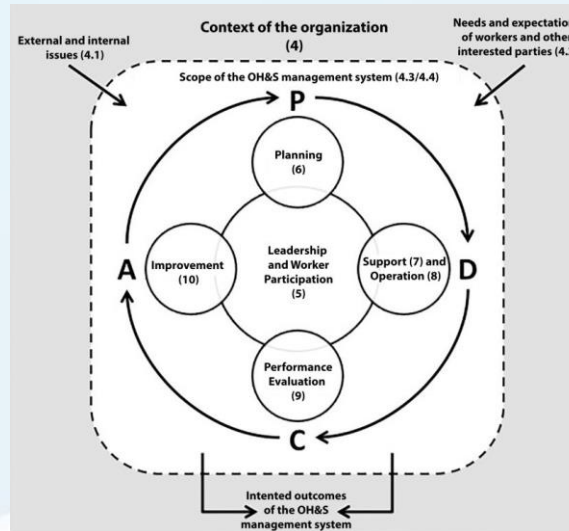
# Process Characteristics – Guidance

- Processes are identified by a series of unique, but consistent, characteristics.
- There are six characteristics of a process that are recommended for effective quality management:
  - A process owner exists;
  - The process is defined;
  - The process is documented;
  - The linkages of the process are established;
  - The process is monitored and improved;
  - Records are necessary.
- The standard does require documented information determined by the organization as being necessary for the effectiveness of the QMS.

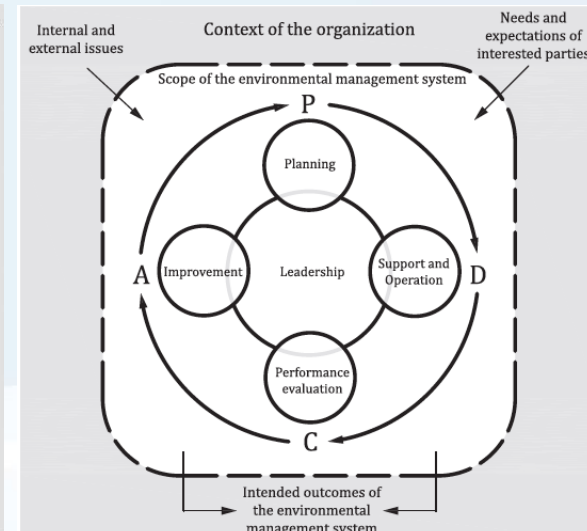
# Integrated Management System Process Model



source: ISO 9001:2015



source: ISO/DIS 14001:2015



source: ISO 45001: 2018

**The PDCA cycle can be applied to all processes and to IMS in whole**

# Quality Management Principles

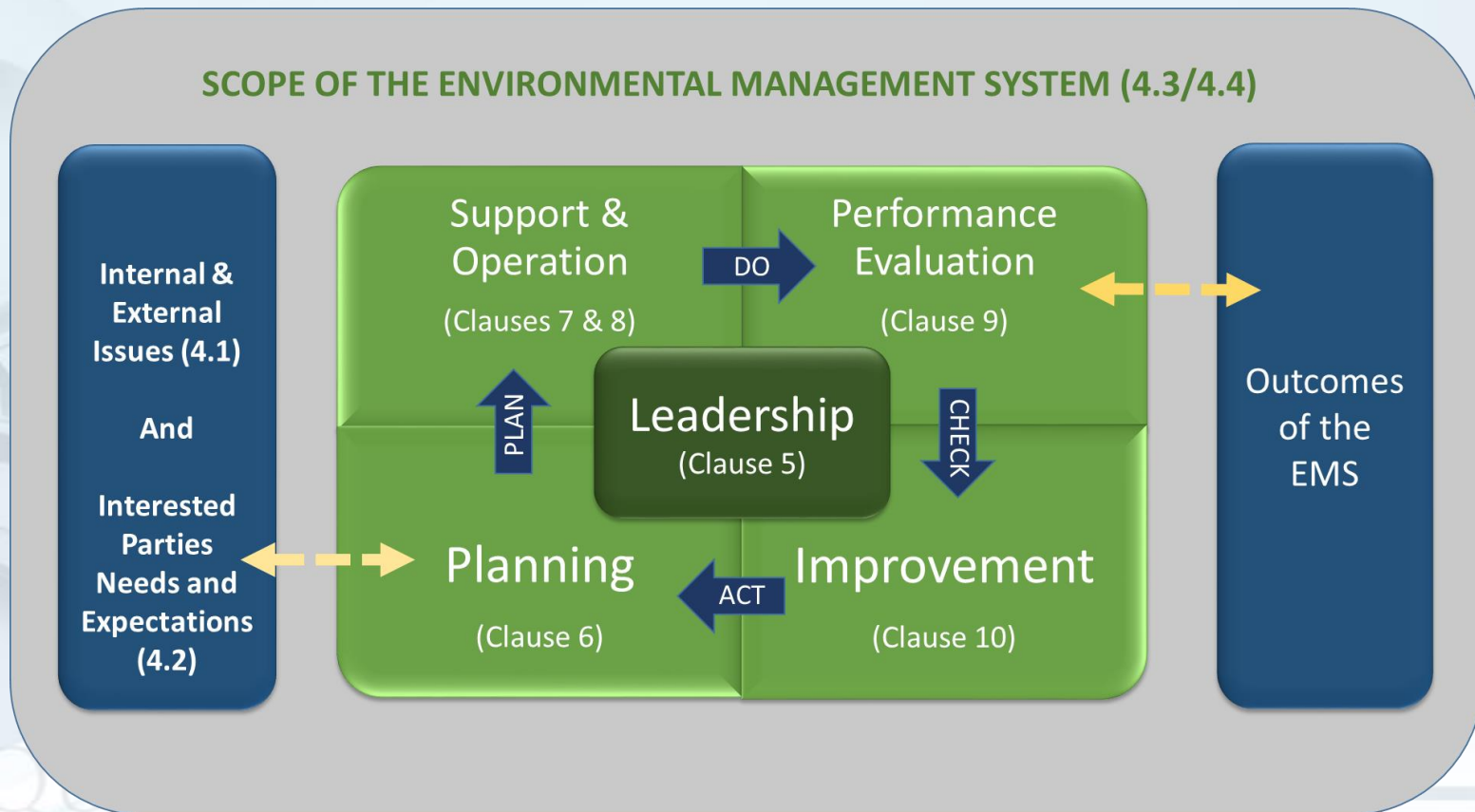
ISO 9001 is based on these quality management principles

## 2015 version (7 Principles):

- Customer Focus
- Leadership
- Engagement of People
- Process Approach
- Improvement
- Evidence-based Decision Making
- Relationship Management

# Environmental Management System Principles

## PDCA Approach



source: ISO 14001:2015



# OH&S Management System Principles

## PDCA Approach

**Context of the organisation**

**Internal & External Issues (4.1)**

**Needs & Expectations of the Interested Parties (4.2)**

**Support (7) & Operation (8)**

**Planning (6)**

**Leadership & Worker Participation**

**Performance Evaluation (9)**

**Outcomes of the OHSMS**

**Improvement (10)**



# Chapter 2: Basic Principles and Methodologies

## — What We Covered

### Learning Objectives

You should now be able to:

- Describe principles and methodologies of the individual standards

### Chapter Agenda

- Basic Principles and Methodologies

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# Chapter 3

## Integrated Management System ISO 9001/ISO14001/ISO 45001 Requirements

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# Chapter 3: IMS Requirements — What We Will Cover

## Learning Objectives

At the end of this chapter, you will be able to:

- List the requirements of the individual standards
- Integrate the requirements into a single IMS

## Chapter Agenda

- Context of the Organization
- Leadership
- Planning
- Support
- Operation
- Performance Evaluation
- Improvement

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# CONTEXT OF THE ORGANIZATION



# Understanding the Organization and its Context

## ISO 9001:2015 – 4.1 Understanding the Organization and its Context

- The organization must determine external and internal issues that are relevant to:
  - its purpose,
  - its strategic direction, and
  - its ability to achieve the intended **result(s) of its QMS.**
- Also must **monitor and review information about external and internal issues.**

## ISO 14001:2015 – 4.1 Understanding the Organization and its Context

- The organization must determine external and internal issues that are relevant to:
  - its purpose, and
  - its ability to achieve the intended outcomes of its **EMS.**
- Also must consider ***environmental conditions being affected by or capable of affecting the organization.***

## ISO 45001: 2018 – 4.1 Understanding the Organization and its Context

- The organization must determine external and internal issues that are relevant to:
  - its purpose and
  - that affect its ability to achieve the intended outcome(s) of OH&S MS

# Context of the Organization – Guidance

- Sources of information about the organization's **external context** may include:
  - Information from stakeholders, e.g., lobby groups, trading partners
  - Laws, regulations, standards, codes of practice, rules of industry regulators, corporate governance rules, and directives
  - The litigation profile of the organization and regulatory action affecting the organization
  - Economic, financial or environmental
  - Analyses from government or industry analysts
  - Media reports

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# Context of the Organization – Guidance

- Sources of information about the organization's **internal context** may include:
  - Key corporate documents such as: policies, strategies, business plans, annual reports, audit reports
  - Organizational structure, definition of legal, compliance, information technology
  - Business partners, e.g., research collaborators, partners, suppliers of products and services
  - Customers
  - Community groups with an interest in the organization
  - Government, including multiple governments for organizations operating across different jurisdictions



# 4.2 Needs and Expectations of Interested Parties

## ISO 9001:2015 – 4.2 Understanding the Needs and Expectations of Interested Parties

- Interested parties can affect the ability of the organization to consistently meet specified requirements.
- Organizations identify *relevant* interested parties and their *relevant* requirements.
- Only interested parties and requirements that are relevant to the QMS are required.
- The organization gathers and reviews information about relevant interested parties and their relevant requirements.

## ISO 14001:2015 – 4.2 Understanding the Needs and Expectations of Interested Parties

- Organizations must determine the interested parties that are relevant to the EMS.
- Organizations must identify the relevant needs and expectations (i.e., requirements) of such interested parties.
- Organizations must determine which of these needs and expectations become its compliance obligations.

## ISO 45001: 2018 – 4.2 Understanding the needs and expectations of workers and other interested parties

The organization must determine:

- interested parties other than workers, that are relevant to the OH&S MS.
- relevant needs and expectations of workers and other interested parties.

needs and expectations that becomes legal requirements & other requirements.



# Interested Parties – Guidance

- Relevant interested parties are those that represent significant risk to organizational sustainability if their needs and expectations are not met.
- Organizations define what results are necessary to be delivered to those relevant interested parties to reduce that risk.
- Interested Parties who perceive themselves to be or could be affected by the EMS must identify themselves.
- For OH&SMS Legal Compliance Agencies, Employees and Customers can be some examples.

# Scope of the IMS

## 4.3 Determining the Scope of the IMS (ISO 9001/ISO 14001/ ISO 45001)

- Identify the limits and applicability of the QMS to establish its scope.
- When determining the scope, the organization considers:
  - The issues referred to in the **Context of the Organization (4.1)**;
  - The requirements of relevant **Interested Parties (4.2)**;
  - Their products and/or services.
  - **Compliance obligations (see 6.1.3)**
  - **Organizational units, functions, and physical boundaries**
  - **Activities, products and services**
  - **Authority and ability to control and influence issues**
  - **planned or performed work related activities.**
- Maintain the scope as documented information and make available to interested parties.
- Once the scope is defined, all activities, products and services of the organization within that scope need to be included in the Integrated Management System.

# Scope of the IMS -Guidance

## Guidance on Scope of the IMS (ISO 9001/ISO 14001/ ISO 45001)

- Note that the scope of a management system may include:
  - The whole organization,
  - Specific identified functions within the organization,
  - Specific and identified sections of the organization, or
  - One or more functions across a group of organizations.

The organization applies all applicable requirements of the standards within the scope:

The organization justifies any requirement of the standard that they determine as **NOT** applicable.

This justification is only valid if those requirements *do not affect the organization's ability* to ensure:

- conformity to requirements and the enhancement of customer satisfaction.
- Meet legal requirements
- Ensure worker and other interested party safety

# IMS Documentation Requirements

## 4.4 Integrated Management System and its Processes

**Documentation is maintained to the extent necessary to establish, implement, maintain and continually improve IMS, including the processes needed and their interactions.**

### 4.4.1 The organization must:

- Determine the inputs and outputs for these processes
- Determine the sequence and interaction of these processes
- Determine and apply criteria, methods and performance indicators needed
- Determine the resources needed and ensure their availability;
- Assign the responsibilities and authorities for these processes;
- Address the risks and opportunities as determined in accordance with 6.1
- Evaluate these processes and implement changes to ensure that these processes achieve their intended results
- Improve the processes and the quality management system

**4.4.2: Maintain documented information to support the operation of the processes, and retain documented information to ensure confidence that the processes are being carried out as planned.**

# IMS Documentation Requirements

- The minimum amount of documentation required by an IMS will be the same for small organization and large organizations.
- The extent can differ between organizations due to:
  - The size of the organization and type of activities
  - The complexity of processes and their interactions
  - The competence of personnel

**See also clause 7.5 Documentation**



# 5. LEADERSHIP



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# Leadership

ISO 9001:2015	ISO 14004:2015	ISO 45001: 2018
5.0 Leadership	5.0 Leadership	5.0 Leadership and Worker Participation
5.1 Leadership and Commitment	5.1 Leadership and Commitment	5.1 Leadership and Commitment
5.2 Policy	5.2 Environmental Policy	5.2 OH&S Policy
5.3 Organizational Roles, Responsibilities and Authorities	5.3 Organizational Roles, Responsibilities and Authorities	5.3 Organizational Roles, Responsibilities and Authorities
		5.4 Consultation and participation of workers

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# Leadership and Commitment

## ISO 9001:2015 – 5.1.1 (Leadership and Commitment) General

### ISO 14001:2015 – 5.1 Leadership and Commitment

- Top management demonstrates leadership and commitment for IMS and:
  - Takes accountability for the effectiveness of the IMS;
  - Ensures policy and objectives are aligned with **Organizational Context** and **Strategic Direction**;
  - Ensures the integration of IMS requirements into business processes;
  - **Promotes the use of the process approach and risk-based thinking (QMS)** ;
  - Makes available the resources for the IMS;
  - Communicates importance of effective management system and conforming to the IMS requirements;
  - Promotes improvement;
  - Supports other relevant management roles to demonstrate leadership as it applies to their areas of responsibility.

Reference to “business” can be interpreted broadly to mean those activities that are core to the purposes of the organization’s existence.

# Leadership and Commitment

## ISO 45001: 2018 Specific Leadership Commitment

*In addition to the requirements in the previous slide Leadership must:*

- develop, lead and promote a culture within the organization that supports the objectives of the OH&S MS
- protect workers from reprisals for reporting incidents, hazards, risks and opportunities;
- ensure the organization establishes and implements a process(es) for consultation and participation of workers (see 5.4);
- consider the need to establish health and safety committees, together with providing support for their functioning.

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# Leadership and Commitment

## ISO 9001:2015 – 5.1.2 Customer Focus /Specific to QMS

- Top management demonstrates leadership and commitment with respect to customer focus by ensuring that:
  - Customer and applicable legal requirements are determined, understood and consistently met;
  - Risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed; and
  - Focus on enhancing customer satisfaction is maintained.

**ISO 14001:2015 and  
ISO 45001: 2018  
do not have this requirement**

# IMS Policy

## ISO 9001:2015 – 5.2.1 Establishing the Quality Policy 5.2.2 Communicating the Quality Policy

## ISO 14001:2015 – 5.2 Environmental Policy

## ISO 45001: 2018– 5.2 OH&S Policy

- Top management establishes, implements and maintains an IMS policy that:
  - Is appropriate to the purpose and context of the organization and supports its strategic direction;
  - Provides a framework for setting IMS objectives;
  - Includes a commitment to satisfy applicable requirements (also legal);
  - Includes a commitment to continual improvement of the IMS.
- The IMS policy must be:
  - Documented;
  - Communicated and understood within the organization;
  - Available to relevant interested parties, as appropriate.

# IMS Policy

## ISO 14001:2015 – 5.2 Environmental Policy Specific Requirements

- Includes a commitment to protect the environment, prevent pollution and other commitments relevant to the context of the organization.
- Includes a commitment to fulfill its compliance obligations.
- Includes a commitment to continual improvement of the EMS to enhance environmental performance.

**Note:** Other specific commitments to protect the environment can include sustainable resource use, climate change mitigation and adaptation, and protection of biodiversity and ecosystem.



# IMS Policy

## ISO 45001: 2018 – 5.2 OH&S Policy Specific Requirements

Top management shall establish, implement and maintain an OH&S policy that:

- includes a commitment to provide safe and healthy working conditions for the prevention of work related injury and/or ill health
- is appropriate to the purpose, the size and context of the organization and to the specific nature of its OH&S risks and OH&S opportunities;
- includes a commitment to eliminate hazards and reduce OH&S risks (see 8.1.2);
- includes a commitment to consultation and participation of workers, and where they exist, workers' representatives.



# Organizational Roles, Responsibilities and Authorities

## ISO 9001:2015 – 5.3 Organizational Roles, Responsibilities and Authorities

- Top management ensures that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.
- Top management must assign the responsibility and authority for:
  - Ensuring that the IMS conforms to the requirements of ISO 9001:2015;
  - Ensuring that the processes are delivering their intended outputs;
  - Reporting on the performance of the quality management system and on opportunities for improvement, in particular to top management;
  - Ensuring the promotion of customer focus throughout the organization;
  - Ensuring that the integrity of the IMS is maintained when changes to the IMS are planned and implemented.

# Organizational Roles, Responsibilities and Authorities

## ISO 14001:2015 – 5.3 Organizational Roles, Responsibilities and Authorities

- Top management must assign the responsibility and authority for:
  - Ensuring that the IMS conforms to the requirements of ISO 14001:2015;
  - Reporting on the performance of the environmental management system, including environmental performance, to top management.

# Organizational Roles, Responsibilities and Authorities

## ISO 45001: 2018 – 5.3 Organisational Roles, Responsibilities and Authorities

Top management ensures that:

- responsibilities and authorities for relevant roles within the OH&S MS are assigned and communicated at all levels within the organization
- Workers at each level of the organization shall assume responsibility for those aspects of OH&S management system over which they have control.
- Roles, Responsibilities and Authorities within the OH&S MS are documented

Top management shall assign the responsibility and authority for:

- ensuring that the OH&S management system conforms to the requirements
- reporting on the performance of the OH&S management system to top management.

**NOTE: While responsibility and authority can be assigned, ultimately, top management is still accountable for the functioning of the OH&S management system.**

# Consultation and Participation

## ISO 45001: 2018 – 5.4 Consultation and Participation of Workers

### **Must establish, implement and maintain a process for:**

- Consultation and participation of workers at all applicable levels and functions
- Involvement of workers' representatives (if they exist) in:
  - the development, planning, implementation,
  - performance evaluation and actions for improvement of the OH&S MS.

### **The organization shall:**

- Provide mechanisms, time, training and resources necessary for consultation and participation;

***NOTE: Worker representation can be a mechanism for consultation and participation.***

- Provide timely access to clear, understandable and relevant information about the OH&S MS;
- Determine and remove obstacles or barriers to participation and minimize those that cannot be removed;

***NOTE: Obstacles and barriers can include failure to respond to worker inputs or suggestions, language or literacy barriers, reprisals or threats of reprisals and policies or practices that discourage or penalize worker participation.***

# Consultation and Participation

## ISO 45001: 2018 – 5.4 Consultation and Participation of Workers

### The organization shall:

- d) Emphasize the consultation of non-managerial workers in:
- determining the needs and expectations of interested parties (4.2)
  - establishing the OH&S policy (5.2)
  - assigning organizational roles, responsibilities and authorities as applicable (5.3)
  - determining how to fulfill legal requirements and other requirements (6.1.3)
  - establishing OH&S objectives and planning to achieve them (6.2)
  - determining controls for outsourcing, procurement and contractors (8.1.4, 8.1.5, and 8.1.6)
  - determining what needs to be monitored, measured and evaluated (9.1.1);
  - planning, establishing, implementing and maintaining an audit program (9.2.2);
  - establishing a continual improvement process(es) (10.2.2);



# Consultation and Participation

## ISO 45001: 2018 – 5.4 Consultation and Participation of Workers

### The organization shall:

- e) emphasize the participation of non-managerial workers in:
- determining the mechanisms for their consultation and participation
  - hazard identification and assessment of risks and opportunities (6.1.1, & 6.1.2)
  - actions to eliminate hazards and reduce OH&S risks (6.1.4)
  - identification of competency, training needs, provision
  - evaluation of training (7.2)
  - determining what needs to be communicated and how this shall be done (7.4)
  - determining, effective implementation and use of controls (8.1, 8.1.3, and 8.2)
  - investigating incidents, nonconformities and determining corrective actions (10.1).

*NOTE: This reference to emphasize the consultation and participation of non-managerial workers is intended to apply to persons carrying out the work activities, but is not intended to exclude, for example, managers who are impacted by work activities or other factors in the organization.*

***NOTE: It is recognized that the provision of training is at no cost to workers and is during working hours, and where possible, can remove significant barriers to worker participation***



# PLANNING





# Planning

ISO 9001:2015	ISO 14004:2015	ISO 45001: 2018
<b>6. Planning</b>	<b>6. Planning</b>	<b>6. Planning</b>
6.1 Actions to Address Risks and Opportunities	6.1 Actions to Address Risks and Opportunities 6.1.1 General 6.1.2 Environmental Aspects 6.1.3 Compliance Obligations 6.1.4 Planning Action	6.1 Actions to address risks and opportunities 6.1.1 General 6.1.2 Hazard identification and assessment of risks and opportunities 6.1.3 Determination of legal requirements and other requirements 6.1.4 Planning action
6.2 Quality Objectives and Planning to Achieve Them	6.2 Environmental Objectives and Planning to Achieve Them 6.2.1 Environmental Objectives 6.2.2 Planning Actions to Achieve Environmental Objectives	6.2 OH&S objectives and planning to achieve them 6.2.1 OH&S objectives 6.2.2 Planning to achieve OH&S objectives
6.3 Planning of Changes	<b>NO EQUIVALENT REQUIREMENT</b>	<b>NO EQUIVALENT REQUIREMENT</b>

# Actions to Address Risks and Opportunities

## ISO 9001:2015 – 6.1 Actions to Address Risks and Opportunities

- **6.1.1:** During planning for the IMS, the organization must consider:
  - the issues from **4.1** and **4.2**
  - determine the risks and opportunities that need to be addressed for the IMS to:
    - Achieve its intended results;
    - Enhance desirable effects;
    - Prevent or reduce undesired effects;
    - Achieve continual improvement.

# Actions to Address Risks and Opportunities

## ISO 14001:2015 – 6.1.1 (Actions to Address Risks and Opportunities) General

- Establish, implement and maintain the processes needed to meet the requirements in **6.1.1** to **6.1.4** by considering:
  - The issues referred to in **4.1**;
  - The requirements referred to in **4.2**;
  - The scope of its environmental management system.
- The organization must also determine the risks and opportunities related to its **environmental aspects (6.1.2)**, **compliance obligations (6.1.3)**, and other issues and requirements identified in **4.1** and **4.2** that need to be addressed in order to:
  - Give assurance the EMS can achieve its intended outcomes;
  - Prevent or reduce undesired effects including the potential for external environmental conditions that affect the organization;
  - Achieve continual improvement.

# Actions to Address Risks and Opportunities

## ISO 14001:2015 – 6.1.1 (Actions to Address Risks and Opportunities) General

- Within the scope of the EMS, the organization must determine potential emergency situations, including those that can have an environmental impact.
- Documented information must be maintained on:
  - Risks and opportunities that need to be addressed;
  - Processes needed in **6.1.1** to **6.1.4**, as necessary to have confidence they are carried out as planned.

**ISO 14001:2015 does not ask for a process map**

# 6.0 Planning

## ISO 45001: 2018 – 6.1 Actions to Address Risks and Opportunities

### 6.1.1 General

- When planning for the OH&S management system, the organization shall consider:
  - the issues referred to in 4.1 (context)
  - the requirements referred to in 4.2 (interested parties)
  - the scope of its OH&S Management System (4.3)
  - determine the risks and opportunities that need to be addressed to:
    - give assurance that the OH&S MS can achieve its intended outcome(s)
    - prevent, or reduce, undesired effects
    - achieve continual improvement.
- In addressing “risks and opportunities”, take into account:
  - OH&S risks,
  - OH&S opportunities and other risks and opportunities to the OH&S MS.

# 6.0 Planning

## ISO 45001: 2018 – 6.1 Actions to Address Risks and Opportunities

### 6.1.1 General

- When determining the risks and opportunities to be addressed, take into account:
  - hazards, risks and opportunities;
  - legal requirements and other requirements (see 6.1.3);
  - risks (6.1.2.2) and opportunities (6.1.2.3) related to operation of OH&S management system that can affect the achievement of the intended outcomes.
- In the planning process, organization must assess:
  - risks and relevant opportunities to intended outcome of the OH&S MS
  - risks associated with changes in organization, its processes, or the OH&S MS
- In the case of planned changes, permanent or temporary, this assessment shall be undertaken before the change is implemented (8.1.3)
- The organization shall maintain documented information on: OH&S risks and opportunities; the processes and actions needed to determine and address its risks and opportunities (6.1.2 to 6.1.4), to the extent necessary to have confidence that they are carried out as planned.



# Actions to Address Risks and Opportunities

## ISO 9001:2015 – 6.1 Actions to Address Risks and Opportunities

- **6.1.2:** The organization must plan actions to address risks and opportunities and determine how to:
  - Integrate and implement actions into its IMS processes;
  - Evaluate the effectiveness of the actions taken.
- Actions taken to address risks and opportunities must be proportionate to the potential impact on the conformity of products and services.
- Actions taken to address risks and opportunities can include:
  - Avoiding risk;
  - Taking risk in order to pursue an opportunity;
  - Eliminating the risk source;
  - Changing the likelihood or consequences;
  - Sharing the risk;
  - Retaining risk by informed decision.
- Opportunities can lead to:
  - Adoption of new practices;
  - Launching new products;
  - Opening new markets;
  - Addressing new customers;
  - Building partnerships;
  - Using new technology.



# Actions to Address Risks and Opportunities

## ISO 14001:2015 – 6.1.2 Environmental Aspects

- Within the scope of the EMS, the organization must determine the environmental aspects and impacts of its activities, products and services that it can control and have influence over, considering a **life cycle perspective**.
- When determining environmental aspects, the following must be taken into account:
  - Change due to planned or new activities and products and services;
  - Abnormal conditions and foreseeable emergency situations;
  - The aspects that have or can have significant impact by using **established criteria**.
- Significant environmental aspects must be communicated among the organization's various levels and functions, as appropriate.
- Documented information must be maintained on:
  - Environmental aspects and associated environmental impacts;
  - Criteria used to determine significant environmental aspects;
  - Significant environmental aspects.

**Note:** Significant environmental aspects can result in risks and opportunities associated with either adverse environmental impacts (threats) or beneficial environmental impacts (opportunities).

# 6.0 Planning

## ISO 45001: 2018 – 6.1 Actions to Address Risks and Opportunities

### 6.1.2 Hazard identification and assessment of risks and opportunities

#### 6.1.2.1 Hazard identification

Organization must establish, implement and maintain processes for:

- On-going and proactive hazard identification
- These processes must take into account but not be limited to:
  - past relevant incidents, internal or external to the organization,
  - including emergencies, and their causes
  - how work is organized
  - social factors such as:
    - ***Workload, work hours, victimization, harassment and bullying***
  - leadership and the culture in the organization
  - routine and non-routine activities and situations, including consideration of:
    - infrastructure, equipment, materials, substances and the physical conditions of the workplace
    - product and service design, research, development, testing, production, assembly, construction, service delivery, maintenance or disposal;
    - human factors
    - how the work is actually done

# 6.0 Planning

## ISO 45001: 2018 – 6.1 Actions to Address Risks and Opportunities

### 6.1.2 Hazard identification and assessment of risks and opportunities

#### 6.1.2.1 Hazard identification

Organization must establish, implement and maintain processes for:

- emergency situations
- people, including consideration of:
  - visitors and other persons
  - those in the vicinity of the workplace who can be affected by the organization
  - workers at a location not under the direct control of the organization
- other issues, including consideration of:
  - the design of work areas, processes, installations, machinery/equipment, operating procedures
  - work organization, including their adaptation to the needs and capabilities of the workers involved
  - situations occurring in the vicinity of the workplace caused by work-related activities under the control of the organization
  - situations not controlled by the organization and occurring in the vicinity of the workplace that can cause injury and/or ill health to persons in the workplace
- actual or proposed changes in organization's operations, processes, activities and OH&S MS (8.1.3) and changes in knowledge of, and information about, hazards.

# 6.0 Planning

## ISO 45001: 2018 – 6.1 Actions to Address Risks and Opportunities

### 6.1.2 Hazard identification and assessment of risks and opportunities

#### 6.1.2.2 Assessment of OH&S risks and other risks to the OH&S MS

The organization shall establish, implement and maintain a processes to:

- assess OH&S risks from the identified hazards, while taking into account legal requirements and other requirements and the effectiveness of existing controls;
- identify and assess the risks related to establishment, implementation, operation and maintenance of OH&S management system that can occur from:
  - the issues identified in 4.1
  - the needs and expectations identified in 4.2.

The organization's methodologies and criteria for the assessment of OH&S risks shall be defined with respect to:

- their scope, nature and timing, to ensure they are proactive rather than reactive and are used in a systematic way.
- Documented information shall be maintained and retained on the methodologies and criteria used.

# 6.0 Planning

## ISO 45001: 2018 – 6.1 Actions to Address Risks and Opportunities

### 6.1.2 Hazard identification and assessment of risks and opportunities

#### 6.1.2.3 Assessment of OH&S opportunities and other opportunities

The organization shall establish, implement and maintain processes to assess:

- opportunities to enhance OH&S performance, while taking into account:
  - opportunities to adapt work, work organization and work environment to workers
  - opportunities to eliminate hazards and reduce OH&S risks
  - planned changes to the organization, its policies, processes or its activities;
- opportunities for improving the OH&S management system.

*OH&S risks and opportunities can result in risks and opportunities to the organization.*



# Actions to Address Risks and Opportunities

## ISO 14001:2015 – 6.1.3 Compliance Obligations

- The organization must:
  - Determine and have access to compliance obligations related to its aspects and apply these compliance obligations to the EMS;
  - Take into account the compliance obligations when establishing, implementing, maintaining and continually improving its EMS.
- Compliance obligations and related activities must be maintained as documented information.

**Note:** *Compliance obligations can result in risks and opportunities to the organization.*

QUALITY



# 6.0 Planning

## ISO 45001: 2018 – 6.1 Actions to Address Risks and Opportunities

### 6.1.3 Determination of legal requirements and other requirements

The organization shall establish, implement and maintain a processes to:

- determine and have access to up-to-date legal requirements and other requirements that are applicable to its hazards, OH&S risks and OH&S management system;
- determine how these legal requirements and other requirements apply to the organization and what needs to be communicated;

746 c) take these legal requirements and other requirements into account when establishing,

747 implementing, maintaining and continually improving its OH&S management system.

748 The organization shall maintain and retain documented information on its legal requirements and other

749 requirements and shall ensure that it is updated to reflect any changes.

750 NOTE Legal requirements and other requirements can result in risks and opportunities to the organization.

# Actions to Address Risks and Opportunities

## ISO 14001:2015 – 6.1.4 Planning Action

- The organization must plan to take actions to address its:
  - Significant environmental aspects;
  - Compliance obligations
  - Risks and opportunities identified in **6.1.1**.
- The organization must also plan how to:
  - Integrate and implement the actions into its EMS and other business processes;
  - Evaluate the effectiveness of these actions (see **9.1**).
- When planning these actions, the organization must consider its technological options and its financial, operational and business requirements.

QUALITY

# 6.0 Planning

## ISO 45001: 2018 – 6.1 Actions to Address Risks and Opportunities

### 6.1.4 Planning Action

The organization shall plan:

- Actions to:
  - address these risks and opportunities (6.1.2.2 and 6.1.2.3);
  - address legal requirements and other requirements (6.1.3);
  - prepare for and respond to emergency situations (8.2);
- How to:
  - integrate and implement the actions into its OH&S management system processes or other business processes;
  - evaluate the effectiveness of these actions.

The organization shall take into account the hierarchy of controls (see 8.1.2) and outputs from the OH&S management system when planning to take action

When planning its actions, the organization shall consider best practices, technological options, financial, operational and business requirements.

# 6.0 Planning

## ISO 9001:2015 – 6.2 Quality Objectives and Planning to Achieve Them

- **6.2.1:** Quality objectives must be established at relevant functions, levels and processes needed for the quality management system.
- The quality objectives must be:
  - Consistent with the quality policy;
  - Measurable;
  - Take into account applicable requirements;
  - Relevant to conformity of products and services;
  - Enhance customer satisfaction;
  - Monitored;
  - Communicated;
  - Updated as appropriate.
- Documented information on the quality objectives must be maintained.

# 6.0 Planning

## ISO 9001:2015 – 6.2 Quality Objectives and Planning to Achieve Them

- **6.2.2:** When planning to achieve quality objectives, the organization must determine:
  - What will be done;
  - What resources will be required;
  - Who will be responsible;
  - When it will be completed;
  - How the results will be evaluated.

QUALITY

# 6.0 Planning

## ISO 14001:2015 – 6.2 Planning Actions to Achieve Environmental Objectives

- When planning how to achieve its environmental objectives, the organization must determine:
  - What will be done;
  - What resources will be required;
  - Who will be responsible;
  - When it will be completed;
  - How the results will be evaluated, including indicators for monitoring progress toward achievement of environmental objectives (see **9.1.1**).
- The organization must consider how actions to achieve its environmental objectives can be integrated into the business processes.

QUALITY



# 6.0 Planning

## ISO 45001: 2018 – 6.2 -OH&S objectives and planning to achieve them

### 6.2.1 OH&S objectives

The organization shall establish OH&S objectives at relevant functions and levels to maintain and improve the OH&S MS and achieve continual improvement in OH&S performance (10.2):

The OH&S objectives shall:

- Be consistent with the OH&S policy;
- be measurable (if practicable) or capable of performance evaluation;
- take into account applicable legal requirements and other requirements;
- take into account the results of the assessment of risks and opportunities ( 6.1.2.2 and 6.1.2.3);
- take into account the result of consultation with workers (see 5.4), and where they exist, workers' representatives;
- be monitored;
- be communicated;
- be updated as appropriate.

# 6.0 Planning

## ISO 45001: 2018 – 6.2 -OH&S objectives and planning to achieve them

### 6.2.2 Planning to achieve OH&S objectives

When planning how to achieve its OH&S objectives, the organization shall determine:

- what will be done;
- what resources will be required;
- who will be responsible;
- when it will be completed;
- how the results will be evaluated and monitored toward achievement of its measurable OH&S objectives;
- how the actions to achieve OH&S objectives will be integrated into the organization's business processes.

The organization shall maintain and retain documented information on the OH&S objectives and plans to achieve them.

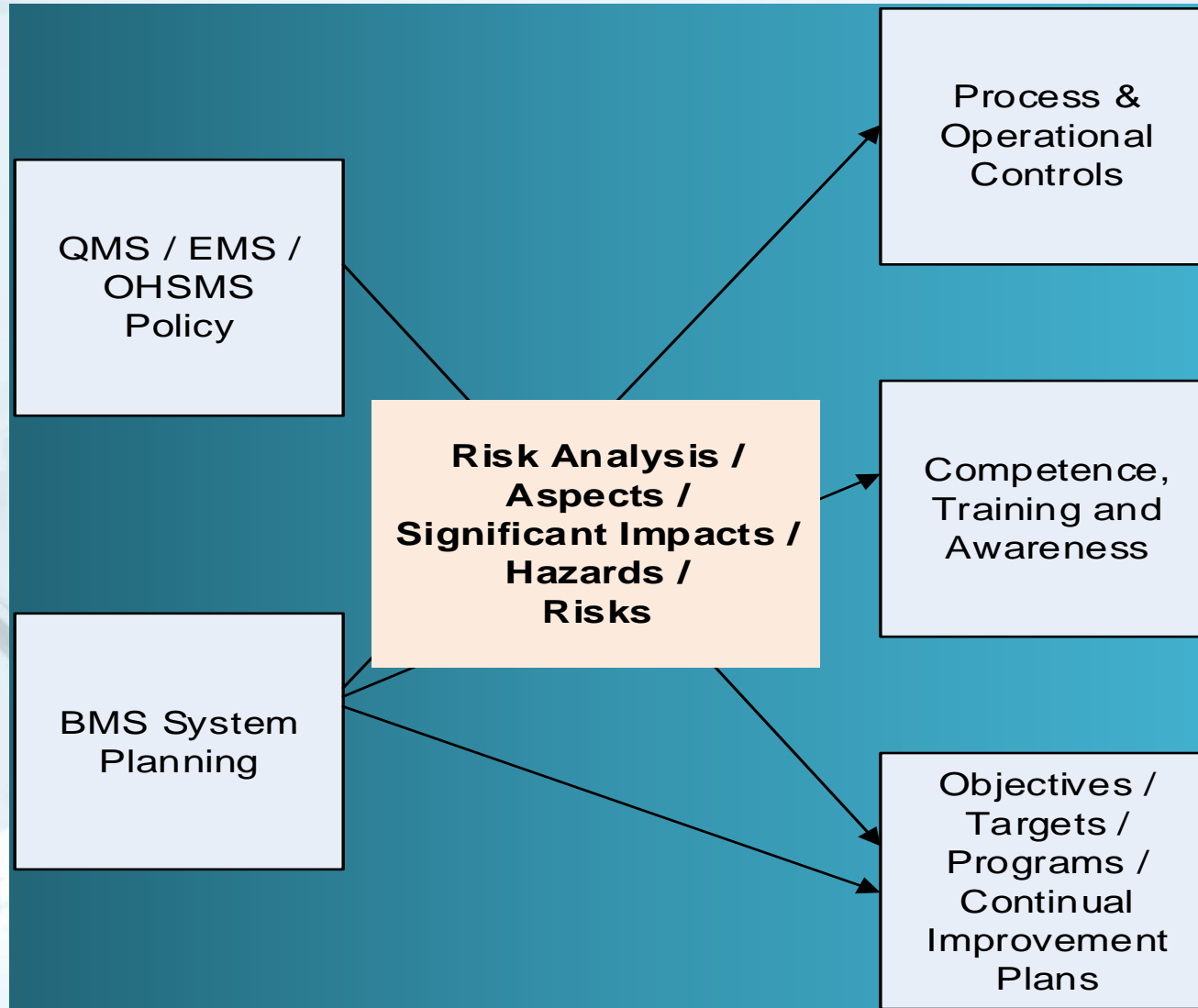
# Planning of Changes

## ISO 9001:2015 – 6.3 Planning of Changes

- When the organization determines the need for changes to the quality management system, the changes must be carried out in a planned manner (see 4.4).
- When planning for changes, the following must be considered:
  - Purpose of the changes and their potential consequences;
  - Integrity of the quality management system;
  - Availability of resources;
  - Allocation or reallocation of responsibilities and authorities.

**Neither ISO 14001:2015 nor ISO 45001: 2018 share this requirement**

# Integrated Risk Assessment Method



# 7.0 SUPPORT



# 7.0 Support

ISO 9001:2015	ISO 14004:2015	ISO 45001: 2018
<p>7.1 Resources</p> <ul style="list-style-type: none"> <li>7.1.1 General</li> <li>7.1.2 People</li> <li>7.1.3 Infrastructure</li> <li>7.1.4 Environment for the operation of processes</li> <li>7.1.5 Monitoring and measuring resources</li> <li>7.1.6 Organizational knowledge</li> </ul>	<p>7.1 Resources</p>	<p>7.1 Resources</p>
<p>7.2 Competence</p>	<p>7.2 Competence</p>	<p>7.2 Competence</p>
<p>7.3 Awareness</p>	<p>7.3 Awareness</p>	<p>7.3 Awareness</p>
<p>7.4 Communication</p>	<p>7.4 Communication</p>	<p>7.4 Communication</p>
<p>7.5 Documented Information</p> <ul style="list-style-type: none"> <li>7.5.1 General</li> <li>7.5.2 Creating and updating</li> <li>7.5.3 Control of documented Information</li> </ul>	<p>7.5 Documented Information</p> <ul style="list-style-type: none"> <li>7.5.1 General</li> <li>7.5.2 Creating and updating</li> <li>7.5.3 Control of documented Information</li> </ul>	<p><b>7.5 Documented Information</b></p> <ul style="list-style-type: none"> <li>7.5.1 General</li> <li>7.5.2 Creating and updating</li> <li>7.5.3 Control of documented Information</li> </ul>



# 7.0 Support

## ISO 9001:2015 – 7.1 Resources

### 7.1.1 General

- The resources necessary to establish, implement, maintain and continually improve the QMS must be determined and provided and must consider:
  - The capabilities of, and constraints on, existing internal resources;
  - What needs to be obtained from external providers.

## ISO 14001:2015 – 7.1 Resources

- The resources necessary to establish, implement, maintain and continually improve the EMS must be determined and provided.

## ISO 45001: 2018 – 7.1 Resources

The organization must determine and provide resources needed for the establishment, implementation, maintenance and continual improvement of the OH&S Management System.

# 7.0 Support

## ISO 9001:2015 – 7.1 Resources

### 7.1.2 -People

- The organization must determine and provide the persons necessary for effective implementation of its QMS and for the operation and control of its processes.

## ISO 9001:2015 – 7.1 -Resources

### 7.1.3 Infrastructure

- The infrastructure needed for the operation of its processes and to achieve conformity of products and services must be determined, provided and maintained.

Note: Infrastructure can include:

- Buildings and associated utilities;
- Equipment, including hardware and software;
- Transportation resources;
- Information and communication technology.

**Neither ISO 14001:2015 nor ISO 45001: 2018 share these requirements**

# 7.0 Support

## ISO 9001:2015 – 7.1 Resources

### 7.1.4 Environment for the Operation of Processes

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

Note: A suitable environment can be a combination of human and physical factors, such as:

- Social (non-discriminatory, calm, non-confrontational);
- Psychological (stress-reducing, burnout prevention, emotionally protective);
- Physical (temperature, heat, humidity, light, airflow, hygiene, noise).

*These factors can differ substantially depending on the products and services provided.*

**Neither ISO 14001:2015 nor ISO 45001: 2018 share these requirements**

# 7.0 Support

## ISO 9001:2015 – 7.1 -Resources

### 7.1.5 Monitoring and measuring resources

#### 7.1.5.1 General

- The organization must determine and provide the resources necessary to ensure valid and reliable results from monitoring or measuring activities used to verify the conformity of products and services.
- The resources provided must be:
  - Suitable for the specific type of monitoring and measurement activities being undertaken;
  - Maintained to ensure their continuing fitness for their purpose.
- Documented information must be retained as evidence of monitoring and measurement resources.

**Neither ISO 14001:2015 nor ISO 45001: 2018 share these requirements**

# 7.0 Support

## ISO 9001:2015 – 7.1 -Resources

### 7.1.5.2 Measurement Traceability

- When measurement traceability is a requirement, or has been determined by the organization to be essential for evidence of confidence in the validity of measurement, the measuring equipment must be:
  - Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national standards (if no such standards, exist, the basis used for calibration or verification must be retained as documented information);
  - Identified in order to determine their status;
  - Safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.
- Appropriate action must be taken if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose.

**Neither ISO 14001:2015 nor ISO 45001: 2018 share these requirements**

# 7.0 Support

## ISO 9001:2015 – 7.1.6 Organizational Knowledge

### 7.1.6 Organizational Knowledge

- The organization must:
  - Determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services;
  - Maintain and make available organizational knowledge as necessary;
  - Determine how to acquire or access necessary additional knowledge and required updates as changes occur.

*Note: Organizational knowledge is knowledge specific to the organization and is general gained by experience. It is information that is used and shared to achieve the organization's objectives and can be based:*

- Internal sources (e.g., intellectual property, knowledge gained from experience, lessons learned from failures and successful projects, capturing and sharing undocumented knowledge and experience, the results of improvements in processes, products and services)
- External sources (e.g., standards, academia, conferences, gathering knowledge from customers or external providers)

**Neither ISO 14001:2015 nor ISO 45001: 2018 share these requirements**



# 7.0 Support

## ISO 9001:2015 – 7.2 Competence

## ISO 14001:2015 – 7.2 Competence

- The organization must:
  - Determine the necessary competence of persons working under its control that affects **the performance and effectiveness of the QMS / *its environmental performance and ability to fulfill compliance obligations***;
  - Ensure that these persons are competent on the basis of education, training or experience;
  - ***Determine training needs associated with environmental aspects and EMS***;
  - Take actions to acquire the necessary competence and evaluate the effectiveness of actions taken;
  - Retain documented information as evidence of competence.

Note: Applicable actions can include the provision of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons.

# 7.0 Support

## ISO 45001: 2018 – 7.2 Competence

### 7.2 Competence

The organization shall:

- Determine the necessary competence of workers that affects or can affect its OH&S performance;
- Ensure that workers are competent (including the ability to identify hazards) on the basis of appropriate education, training, or experience; O\*M\*N\*E\*X\*
- Where applicable, take actions to acquire and maintain the necessary competence, and evaluate the effectiveness of the actions taken;
- Retain appropriate documented information as evidence of competence.

*NOTE: Applicable actions can include, for example : the provision of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons.*

# 7.0 Support

## ISO 9001:2015 – 7.3 Awareness

## ISO 14001:2015 – 7.3 Awareness

- All personnel doing work under the organization’s control must be aware of:
  - **The quality policy / *the environmental policy***;
  - **Relevant quality objectives / *significant environmental aspects and related actual or potential impact associated with their work***;
  - Their contribution to the effectiveness of the **quality management system including the benefits of improved performance / *environmental management system including the benefits of enhanced environmental performance***;
  - The implications of not conforming with **quality management system requirements / *environmental management system requirements, including not fulfilling the compliance obligations***.

QUALITY

# 7.0 Support

## ISO 45001: 2018– 7.3 -Awareness

Workers shall be made aware of:

- OH&S policy and OH&S objectives;
- Their contribution to the effectiveness of the OH&S MS, including the benefits of improved OH&S performance;
- Implications and potential consequences of not conforming with the OH&S MS requirements;
- Incidents, and outcomes of their investigation, that are relevant to the workers;
- Hazards, OH&S risks and actions determined, that are relevant to the workers;
- Arrangements providing workers the ability to remove themselves from work situations that they believe would present an imminent and serious danger:
  - To their life or health,
  - In protecting them from undue consequences for doing so.

# 7.0 Support

## ISO 9001:2015 – 7.4 Communication

- Determine the internal and external communications relevant to the quality management system, including:
  - On what to communicate;
  - When to communicate;
  - With whom to communicate;
  - How to communicate;
  - Who communicates.

QUALITY

# 7.0 Support

## ISO 14001:2015 – 7.4 – Communication

### 7.4.1 General

- Establish, implement and maintain processes needed for internal and external communications relevant to the EMS, including:
  - On what to communicate;
  - When to communicate;
  - With whom to communicate;
  - How to communicate.
- When establishing communication processes, the organization must:
  - Take into account its compliance obligations;
  - Ensure that environmental information communicated is consistent with information generated within the EMS and is reliable.
- The organization must respond to relevant communications on EMS and retain documented information as evidence of its communication.



# Communication

## ISO 14001:2015 – 7.4 -Communication

### 7.4.2 –Internal Communication

- The organization must:
  - Internally communicate information relevant to the EMS among various levels and functions, including changes to the EMS, as appropriate;
  - Ensure its communication processes enable personnel doing work under its control to contribute to continual improvement.

## ISO 14001:2015 – 7.4 -Communication

### 7.4.3 –External Communication

- The organization must externally communicate information relevant to the EMS, as established by its communication processes and as required by its compliance obligations.

# 7.0 Support

## ISO 45001: 2018 –7.4 - Communication

### 7.4.1 General

The organization must establish, implement and maintain the processes needed for the internal and external communications relevant to the OH&S MS, including determining:

- On what it will communicate;
- When to communicate;
- With whom to communicate:
  - internally among the various levels and functions of the organization;
  - among contractors and visitors to the workplace;
  - among other interested parties;
- how to communicate.

# 7.0 Support

## ISO 45001: 2018 –7.4 - Communication

### 7.4.1 General

The organization shall take into account diversity aspects (for example gender, 833 language, culture, literacy, disability), when considering its communication needs.

The organization shall ensure that the views of external interested parties are considered in establishing its communication processes.

When establishing its communication processes, the organization shall:

- Take into account its legal requirements and other requirements;
- Ensure that OH&S information to be communicated is consistent with information generated within the OH&S management system, and is reliable.

The organization shall:

- respond to relevant communications on its OH&S management system.
- retain documented information as evidence of its communications, as appropriate.

# 7.0 Support

## ISO 45001: 2018 –7.4 - Communication

### 7.4.2 Internal Communication

The organization shall:

- Internally communicate information relevant to the OH&S MS among various levels and functions of the organization, including changes, as appropriate;
- Ensure its communication processes enables workers to contribute to continual improvement.

### 7.4.3 External communication

The organization must externally communicate information relevant to the OH&S MS, as established by the organization's communication processes and as required by its legal and other requirements.

# 7.0 Support

**ISO 9001:2015 – 7.5 - Documented Information**

***ISO 14001:2015 – 7.5 - Documented Information***

***ISO 45001: 2018 – 7.5 – Documented Information***

## 7.5.1 General

- The IMS must include documented information that is:
  - Required by the applicable standards;
  - Determined by the organization as being necessary for an effective IMS
  - ***documented information required by legal requirements and other requirements***

Note: The extent of documented information can differ from one organization to another due to the:

- Size of the organization and its type of activities, processes, products and services;
- Complexity of processes and their interactions;
- Competence of persons doing work under its control;
- ***Need to demonstrate fulfillment of its compliance obligations (EMS only)***
- ***Need to demonstrate fulfillment of legal and other requirements (OH&S)***

**There is NO difference in MINIMUM documentation requirements between small and large organizations**

# 7.0 Support

**ISO 9001:2015 – 7.5 - Documented Information**

**ISO 14001:2015 – 7.5 - Documented Information**

**ISO 45001: 2018 – 7.5 - Documented Information**

## 7.5.2 Creating and Updating

- When creating and updating documented information, the organization must ensure appropriate:
  - Identification and description (e.g., title, date, author, or reference number);
  - Format (e.g., language, software version, graphics) and media (e.g., paper, electronic);
  - Review and approval for suitability and adequacy.



# 7.0 Support

## ISO 9001:2015 – 7.5 - Documented Information

## ISO 14001:2015 – 7.5 - Documented Information

### 7.5.3. Control of Documented Information

- **7.5.3.1** Documented information required by the standards must be controlled to ensure that it is:
  - Available and suitable for use, where and when it is needed;
  - Adequately protected (e.g., from loss of confidentiality, improper use, or loss of integrity).
- **7.5.3.2** For the control of documented information, the following activities must be addressed as applicable:
  - Distribution, access, retrieval and use;
  - Storage and preservation, including preservation of legibility;
  - Control of changes (e.g., version control);
  - Retention and disposition.

# 7.0 Support

**ISO 9001:2015 – 7.5.3 Control of Documented Information (as 7.5.3.1 & 7.5.3.2)**

**ISO 14001:2015 – 7.5.3 Control of Documented Information**

- Documented information of external origin determined as necessary for the planning and operation of the QMS must be identified and controlled.
- **Documented information retained as evidence of conformity must be protected from unintended alterations. (QMS only)**

NOTE: Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change documented information.

***Document Control requirements for ISO 45001: 2018 are basically the same. See next slide***

# 7.0 Support

## ISO 45001: 2018 – 7.5 Documented Information

### 7.5.3 Control of documented Information

Documented information required by the OH&S MS must be controlled to ensure:

- It is available and suitable for use, where and when it is needed;
- It is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

For the control of documented information, the organization shall address the following activities, as applicable:

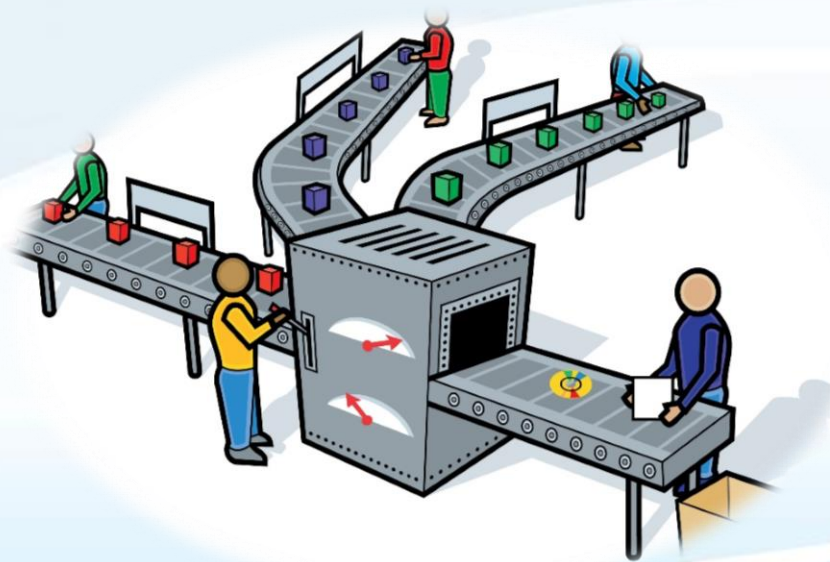
- Distribution, access, retrieval and use;
- Storage and preservation, including preservation of legibility;
- Control of changes (e.g. version control);
- Retention and disposition.

Documented information of external origin determined by the organization to be necessary for the planning and operation of the OH&S MS shall be identified, as appropriate, and controlled.

#### NOTES

- **Access can imply a decision regarding the permission to view , or the permission and authority to view and change .**
- **Access to relevant documented information includes access by workers, and where they exist, workers representatives.**

# 8.0 OPERATION



QUALITY

# 8.0 Operation

ISO 9001:2015	ISO 14004:2015	ISO 45001: 2018
8.1 Operational Planning and Control	8.1 Operational Planning and Control	8.1 Operational planning and control 8.1.1 General 8.1.2 Eliminating hazards and reducing OH&S risks 8.1.3 Management of change
8.2 Requirements for Products and Services	No ISO 14001:2015 Equivalent	No ISO 45001: 2018 Equivalent
No ISO 9001:2015 Equivalent	8.2 Emergency Preparedness & Response	8.2 Emergency preparedness and response
8.3 Design and Development of Products and Services	No ISO 14001:2015 Equivalent	No ISO 45001: 2018 Equivalent

# 8.0 Operation

## ISO 9001:2015 – 8.1 Operational Planning and Control

- Plan, implement and control the processes and actions determined in Clause 6 to meet the requirements for the provision of products and services by:
  - Determining the requirements for products and services;
  - Establishing criteria for the processes and the acceptance of products and services;
  - Determining the resources needed to achieve conformity to the product and service requirements;
  - Implementing process control in accordance with the criteria;
  - Determining, maintaining and retaining documented information needed to have confidence that processes are carried out as planned and demonstrate conformity of products and services to their requirements.
- Output of this planning must be suitable to the operations.
- Control planned changes and review the consequences of intended changes.
- Take action to mitigate adverse effects, as necessary.
- Must ensure that outsourced processes are controlled.



# 8.0 Operation

## ISO 14001:2015 – 8.1 Operational Planning and Control

- Establish, implement, control and maintain processes needed to meet EMS requirements, and the actions identified in **6.1** and **6.2**, by:
  - Establishing operating criteria for the processes;
  - Implementing control of the processes, in accordance with the operating criteria.  
Note: Controls can include engineering controls and procedures.
- Controls can be implemented individually or in combination in the following hierarchy:
  - Elimination;
  - Substitution;
  - Administrative.
- Control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects.
- Ensure outsourced sources are controlled or influenced.
- Type and extent of control or influence must be defined within the EMS.

# 8.0 Operation

## ISO 14001:2015 – 8.1 Operational Planning and Control

- Consistent with a life cycle perspective, the organization must:
  - Establish controls to ensure its environmental requirements are addressed in the design and development process for product or service, considering each life cycle stage;
  - Determine its environmental requirements for the procurement of products and services, as appropriate;
  - Communicate its relevant environmental requirements to external providers, including contractors;
  - Consider the need to provide information about significant environmental impacts associated with the transportation or delivery, use, end-of-life treatment and final disposition of its products and services.
- Maintain documented information to the extent necessary to have confidence that the processes have been carried out as planned.

# 8.0 Operation

## ISO 45001: 2018 – 8.1 Operational Planning and Control

### 8.1.1 General

The organization shall plan, implement, control and maintain the processes needed to meet requirements of the OH&S management system, and to implement the actions determined in Clause 6, by:

- Establishing criteria for the processes
- Implementing control of the processes in accordance with the criteria;
- Maintaining and retaining documented information to the extent necessary to have confidence that processes are carried out as planned;
- Adapting work to workers.

***At multi-employer workplaces, the organization shall coordinate the relevant parts of the OH&S MS with the other organizations.***

# 8.0 Operation

## ISO 45001: 2018 – 8.1 Operational Planning and Control

### 8.1.2 Eliminating hazards and reducing OH&S risks

The organization shall establish, implement and maintain processes for elimination of hazards and reduction of OH&S risks using the following hierarchy of control:

- Eliminate the hazard;
- Substitute with less hazardous materials, processes, operations or equipment;
- Use engineering controls and/or reorganization of work;
- Use of administrative controls, including training;
- Use of adequate personal protective equipment.

NOTE 1: In many countries, legal requirements and other requirements include the requirement that personal protective equipment (PPE) is provided at no cost to workers.

# 8.0 Operation

## ISO 45001: 2018 – 8.1 Operational Planning and Control

### 8.1.3 Management of change

The organization shall establish processes for the implementation and control of planned temporary and permanent changes that impact OH&S performance including:

a) new or changes to products, services and processes, including:

- working conditions;
- workplace locations and surroundings;
- equipment;
- work organization;
- work force;

b) changes to legal requirements and other requirements;

c) changes in knowledge or information about hazards and related OH&S risks;

d) developments in knowledge and technology.

The organization shall and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

***NOTE Changes can result in potential OH&S opportunities.***





# 8.0 Operation

## ISO 45001: 2018 – 8.1 Operational Planning and Control

### 8.1.4.1 Procurement

The organization must establish, implement and maintain processes to control the procurement of products and services in order to ensure their conformance with its OH&S MS.

### 8.1.4.2 Contractors

Coordinate with contractors to control OH&S risks arising from

- a) the contractors' activities and operations that impact the organization;
- b) the organization's activities and operations that impact the contractors' workers;
- c) the contractors' activities and operations that impact other interested parties in the workplace

Ensure OH&S MS by defining & applying OH&S criteria for the selection of contractors.

### 8.1.4.3 Outsourcing

The organization shall ensure that outsourced processes are controlled. The type and degree of control to be applied to these processes shall be defined within the OH&S MS.

***NOTE Consultation with external providers can assist an organization to address any impact outsourcing has on its OH&S performance.***



# 8.0 Operation

## ISO 45001: 2018 – 8.1 Operational Planning and Control

### 8.1.4.2 Contractors

The organization must establish processes, in coordination with its contractor(s), for hazard identification and to assess and control the OH&S risks, arising from the:

- Contractors' activities and operations that impact the organization;
- Organization's activities and operations that impact contractors' workers;
- Contractors' activities and operations that impact other interested parties in the workplace.

The organization shall establish and maintain processes to ensure that the requirements of the OH&S MS are met by contractors and their workers.

These processes shall define and apply occupational health and safety criteria for the selection of contractors.

***NOTE It can be helpful to include the occupational health and safety criteria for the selection of contractors in the contractual documents.***

# 8.0 Operation

## ISO 9001:2015 – 8.2 – Requirements for Products and Services

### 8.2.1 Customer Communication

- Customer communication must have information related to:
  - Products and services;
  - Handling enquiries, contracts or orders, including changes;
  - Obtaining customer feedback related to products and services, including customer complaints;
  - Handling or controlling customer property;
  - Establishing specific requirements for contingency actions, when relevant.

## ISO 9001:2015 – 8.2 – Requirements for Products and Services

### 8.2.2 Determining the Requirements for Products and Services

- When determining the requirements for customer products and services, the organization must ensure that:
  - The requirements for the products and services are defined, including any applicable statutory and regulatory requirements, and others considered necessary by the organization;
  - The organization can meet its claims for the products and services it offers.

# 8.0 Operation

## ISO 9001:2015 – 8.2 – Requirements for Products and Services

### 8.2.3 Review of the Requirements for Products and Services

- **8.2.3.1:** The organization must ensure that it has the ability to meet requirements for products and services offered to customers by conducting a review of the following prior to committing to supply products and services:
  - Requirements specified by the customer, including delivery and post-delivery activities;
  - Requirements not stated by the customer, but necessary for the specified or intended use;
  - Requirements specified by the organization;
  - Statutory and regulatory requirements applicable to the products and services;
  - Contract or order requirements differing from those previously expressed.
- The organization must ensure changes to contract or order requirements are resolved.
- When the customer does not provide documented statements of requirements, such requirements must be confirmed by the organization before acceptance.

# 8.0 Operation

## ISO 9001:2015 – 8.2 –Requirements for Products and Services

### 8.2.3 Review of the Requirements for Products and Services

- **8.2.3.2:** Documented information must be retained on the following, as applicable:
  - Results of the review;
  - Any new requirements for the products and services.

## ISO 9001:2015 – 8.2 –Requirements for Products and Services

### 8.2.4 Changes to requirements for products and services

- When changes for products and services occurs, the organization must ensure that:
  - Relevant documented information is amended;
  - Relevant persons are made aware of the changed requirements.

**Neither ISO 14001:2015 nor ISO 45001: 2018 share product or service requirements. Instead, they have requirements for Emergency Preparedness and Response.**

# 8.0 Operation

## ISO 14001:2015 – 8.2 Emergency Preparedness and Response

- Establish, implement and maintain processes needed to prepare for and response to potential emergency situations identified in **6.1.1**.
- The organization must:
  - Prepare to respond by planning actions to prevent or mitigate adverse environmental impacts from emergency situations;
  - Respond to actual emergency situations;
  - Take action to prevent or mitigate the consequences of emergency situations, appropriate to the extent of the emergency and potential environmental impact;
  - Periodically test the planned response actions, where practicable;
  - Periodically review and revise the processes and planned response actions, in particular after the occurrence of emergency situations or tests;
  - Provide relevant information and training related to emergency preparedness and response, as appropriate, to relevant interested parties, including personnel working under its control.
- Maintain documented information to the extent necessary to have confidence that the processes have been carried out as planned.



# 8.0 Operation

## ISO 45001: 2018 – 8.2- Emergency Preparedness and Response

### 8.2 Emergency preparedness and response

Must establish, implement and maintain processes needed to prepare for and respond to potential emergency situations, as identified in 6.1.2.1, including:

- Establishment of a planned emergency response and provision of first aid;
- Periodic testing and exercise of planned response capability;
- Performance evaluation and, as necessary, revision of the planned response, including after testing and in particular after the occurrence of emergency situations;
- Communication and provision of relevant information to all workers on their duties and responsibilities;
- Provision of training for the planned response;
- Communication of relevant information to contractors, visitors, emergency response services, government authorities and, as appropriate, the local community;
- Taking into account the needs and capabilities of all relevant interested parties and ensuring their involvement, as appropriate, in the development of the planned response.

The organization shall maintain and retain documented information on the processes and on the plans for responding to potential emergency situations.



# 8.0 Operation

## ISO 9001:2015 – 8.3 - Design and Development of Products and Services

### 8.3.1 General

- Establish, implement and maintain a design and development process appropriate to ensure the subsequent provision of products and services.

## ISO 9001:2015 – 8.3 - Design and Development of Products and Services

### 8.3.2 Design and Development Planning

- In determining the stages and controls for design and development, the organization must consider the:
  - Nature, duration and complexity of the design and development activities;
  - Process stages, including applicable design and development reviews;
  - Design and development verification and validation activities;
  - Responsibilities and authorities for the design and development process;
  - Internal and external resources needed for the design and development;
  - Need to control interfaces between persons involved in the process;
  - Need for involvement of customers and users;
  - Requirements for subsequent provision of products and services;
  - Level of control expected by customers and other relevant interested parties;
  - Documented information needed to demonstrate that design and development requirements have been met.

# 8.0 Operation

## ISO 9001:2015 – 8.3 - Design and Development of Products and Services

### 8.3.3 Design and Development Inputs

- Determine the requirements essential for the specific type of products and services to be design and developed, considering:
  - Functional and performance requirements;
  - Information derived from previous similar design activities;
  - Statutory and regulatory requirements;
  - Standards and codes of practice to which the organization has committed;
  - Potential consequences of failure due to the nature of products and services.
- Design inputs must be adequate, complete and unambiguous.
- Conflicting design and development inputs must be resolved.
- Documented information on design and development inputs must be retained.

# 8.0 Operation

## ISO 9001:2015 – 8.3 - Design and Development of Products and Services

### 8.3.4 Design and Development Controls

- Apply controls to the design and development process to ensure that:
  - Results to be achieved are defined;
  - Design reviews are conducted to evaluate the ability of the results of design and development to meet requirements;
  - Verification activities are conducted to ensure that the design and development outputs meet the input requirements;
  - Validation activities are conducted to ensure that resulting products and services meet the requirements for intended use;
  - Necessary actions are taken on problems determined during the reviews, or verification and validation activities;
  - Documented information of these activities is retained.

Note: Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization.

# 8.0 Operations

## ISO 9001:2015 – 8.3.5 Design and Development Outputs

### 8.3.5 Design and Development Outputs

- Ensure that design and development outputs:
  - Meet the input requirements;
  - Are adequate for the subsequent processes;
  - Include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;
  - Specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.
- Documented information on design and development outputs must be retained.
- Identify, review and control changes during, or subsequent to, the design and development of products and services to the extent necessary to ensure that there is no adverse impact on conformity to requirements.
- Documented information on design and development outputs must be retained on:
  - Design and development changes;
  - Results of reviews;
  - Authorization of the changes;
  - Actions taken to prevent adverse impacts.

# 8.0 Operation

ISO 9001:2015	ISO 14004:2015	ISO 45001: 2018
8.1 Operational Planning and Control	8.1 Operational Planning and Control	8.1 Operational planning and control
8.2 Requirements for Products and Services	No ISO 14001:2015 Equivalent	No ISO 45001: 2018 Equivalent
No ISO 9001:2015 Equivalent	8.2 Emergency Preparedness & Response	8.2 Emergency preparedness and response
8.3 Design and Development of Products and Services	No ISO 14001:2015 Equivalent	No ISO 45001: 2018 Equivalent

**As a Group Discuss the feasibility and advantage of integrating Clause 8.1 thru 8.3 in your organization and share with the class as time allows**

# 8.0 Operation

ISO 9001:2015	ISO 14004:2015	ISO 45001: 2018
8.4 Control of Externally Provided Processes, Products and Services 8.4.1 General 8.4.2 Type and extent of control 8.4.3 Information for external providers	<b>No ISO 14001:2015 Equivalent</b>	8.1.4 Outsourcing 8.1.5 Procurement 8.1.6 Contractors
8.5 Production and Service Provision	<b>No ISO 14001:2015 Equivalent</b>	<b>No ISO 45001: 2018 Equivalent</b>
8.6 Release of Products and Services	<b>No ISO 14001:2015 Equivalent</b>	<b>No ISO 45001: 2018 Equivalent</b>
8.7 Control of Nonconforming Outputs	<b>No ISO 14001:2015 Equivalent</b>	<b>No ISO 45001: 2018 Equivalent</b>

QUALITY





# 8.0 Operation

## ISO 9001:2015 – 8.4 - Control of Externally Provided Processes, Products and Services

### 8.4.1 General

- Ensure that externally provided processes, products and services conform to requirements.
- Determine controls to be applied to externally provided processes, products and services when such products and services are:
  - Intended for incorporation into the organization's own products and services;
  - Provided directly to the customers by the external provider on behalf of the organization;
  - Fully or partly provided as a result of a decision by the organization.
- Determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers based on their ability to provide processes or products and services in accordance with the organization's requirements.
- Documented information on these activities and any necessary actions arising from the evaluations must be retained.

# 8.0 Operation

## ISO 45001: 2018 – 8.1.4 Procurement/ Contractors/ Outsourcing

### 8.1.4 Procurement

Organization must establish, implement and maintain a processes to control the procurement of products and services in order to ensure their conformance with its OH&S management system

#### 8.1.4.3 Outsourcing

Outsourced processes are controlled.

The type and degree of control applied to these processes are defined within the OH&S management system.

*NOTE: Consultation with external providers can assist an organization to address any impact outsourcing has on its OH&S performance.*

# 8.0 Operation

## ISO 45001: 2018 – 8.1.4.2 Contractors

### 8.1.4.2 Contractors

The organization must establish a processes, in coordination with its contractors, for hazard identification and to assess and control the OH&S risks, arising from the:

- a) contractors' activities and operations that impact the organization;
- b) organization's activities and operations that impact contractors' workers;
- c) contractors' and other interested parties activities and operations

The organization must also establish and maintain processes to make sure that the requirements of the it's OH&S MS are met by contractors and their workers.

These processes must define and apply occupational health and safety criteria for the selection of contractors.

*NOTE: It can be helpful to include the occupational health and safety criteria for the selection of contractors in the contractual documents.*

# 8.0 Operation

## ISO 9001:2015 – 8.4 - Control of Externally Provided Processes, Products and Services

### 8.4.2 Type and Extend of Control

- Ensure that externally provided processes, products and services conform to requirements:
  - Ensure that outsourced processes remain within the control of the QMS;
  - Define the controls for external providers and products supplied;
  - Take into consideration the potential impact of externally provided processes, products and services to meet customer and applicable legal requirements, and the effectiveness of the controls applied by the external provider;
  - Determine the verification, or other actions necessary, to ensure that externally provided processes, products and services to meet requirements.

# 8.0 Operation

## ISO 9001:2015 – 8.4 - Control of Externally Provided Processes, Products and Services

### 8.4.3 Information for External Providers

- Review and ensure the adequacy of requirements prior to communication to external provider.
- Requirements for the following must be communicated to external providers:
  - The processes, products and services to be provided;
  - The approval of:
    - 1) products and services;
    - 2) methods, processes and equipment;
    - 3) the release of products and services;
  - Competence, including any required qualification of persons;
  - External providers' interactions with the organization;
  - Control and monitoring of supplier's performance by the organization;
  - Verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.

# 8.0 Operation

## ISO 9001:2015 – 8.5 – Production and Service Provision

### 8.5.1 Control of Production and Service Provision

- Production and service provision must be implemented under controlled conditions, which must include, as applicable:
  - Availability of documented information that defines the characteristics of, and results to be achieved by the products, services or activities to be performed;
  - Availability and use of suitable monitoring and measuring resources;
  - Implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes and acceptance for products and services are met;
  - Use of suitable infrastructure and environment for the operation of processes;
  - Appointment of competent persons, including any required qualification;
  - Validation and periodic revalidation of the ability to achieve planned results of processes, production and service where the resulting output cannot be verified by subsequent monitoring or measurement;
  - Implementation of actions to prevent human error;
  - Implementation of release, delivery and post-delivery activities.



# 8.0 Operation

## ISO 9001:2015 – 8.5 – Production and Service Provision

### 8.5.2 Identification and Traceability

- The organization must use suitable means to identify outputs to ensure the conformity of products and services, as necessary.
- The organization must identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.
- The organization must control the unique identification of the outputs when traceability is a requirement and must retain the documented information necessary to enable traceability.

## ISO 9001:2015 – 8.5 – Production and Service Provision

### 8.5.3 Property belonging to Customers or External Providers

- While under the control or use of the organization property belonging to customers or suppliers must be identified, verified and safeguarded.
- If customer/supplier property is lost, damaged or otherwise found to be unsuitable for use, documented information on what has occurred must be retained and reported to the owner.

*Note: A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data.*

# 8.0 Operation

## ISO 9001:2015 – 8.5 – Production and Service Provision

### 8.5.4 Preservation

- Preserve products and services during production, transmission and transportation to the extent necessary to ensure conformity to requirements.

Note: Preservation can include identification, handling, contamination control, packaging, storage.

## ISO 9001:2015 – 8.5 – Production and Service Provision

### 8.5.5 Post-Delivery Activities

- Ensure that requirements for post-delivery activities associated with the products and services are met to the extent necessary.
- In determining the extent of required post-delivery activities, consider:
  - Statutory and regulatory requirements;
  - Potential undesired consequences associated with its products and services;
  - Nature, use and intended lifetime of its products and services;
  - Customer requirements;
  - Customer feedback.

Note: Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

# 8.0 Operation

## ISO 9001:2015 – 8.5 – Production and Service Provision

### 8.5.6 Control of Changes

- The organization must review and control changes for production or service provision to the extent necessary to ensure continuing conformity with requirements.
- Documented information that describes the following must be retained:
  - The results of the review of changes;
  - The person(s) authorizing the change;
  - Any necessary actions arising from the review.

QUALITY

# 8.0 Operation

## ISO 9001:2015 – 8.6 – Release of Products and Services

### 8.6 Release of Products and Services

- Implement planned arrangements at appropriate stages to verify that the product and service meets requirements.
- Products and services must not be released to customers until the planned arrangements are achieved, unless approved by a relevant authority and, as applicable, by the customer.
- Documented information on product release must be retained and include the following:
  - Evidence of conformity with the acceptance criteria;
  - Traceability to the person(s) authorizing the release.

QUALITY

# 8.0 Operation

## ISO 9001:2015 – 8.7– Control of Nonconforming Outputs

**8.7.1** Organization must ensure that outputs that do not conform to requirements are identified and controlled to prevent their unintended use or delivery.

- Take appropriate action based on nature of nonconformity and its effect on conformity of products and services.
  - This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.

Organization deals with nonconforming outputs in one or more of the following ways:

- Correction;
- Segregation, containment, return or suspension of provision of products and services;
- Informing the customer;
- Obtaining authorization for acceptance under concession.

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

# 8.0 Operation

## ISO 9001:2015 – 8.7– Control of Nonconforming Outputs

**8.7.2** The organization shall retain documented information that:

- a) describes the nonconformity;
- b) describes the actions taken;
- c) describes any concessions obtained;
- d) identifies the authority deciding the action in respect of the nonconformity.

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# 9.0 PERFORMANCE EVALUATION



QUALITY

# 9.0 Performance Evaluation

ISO 9001:2015	ISO 14004:2015	ISO 45001: 2018
9.1 Monitoring, Measurement, Analysis and Evaluation 9.1.1 General 9.1.2 Evaluation of compliance	9.1 Monitoring, Measurement, Analysis and Evaluation 9.1.1 General 9.1.2 Evaluation of compliance	9.1 Monitoring, Measurement, Analysis and Evaluation 9.1.1 General 9.1.2 Evaluation of compliance
9.2 Internal Audit 9.2.1 General 9.2.2 Internal audit program	9.2 Internal Audit 9.2.1 General 9.2.2 Internal audit program	9.2 Internal audit 9.2.1 General 9.2.2 Internal audit program
9.3 Management Review 9.3.1 General 9.3.2 Management review inputs. 9.3.3 Management review outputs	9.3 Management Review	9.3 Management review

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# 9.0 Performance Evaluation

## ISO 9001:2015 – 9.1 - Monitoring, Measurement, Analysis and Evaluation

### 9.1.1 General

- The organization must determine:
  - What needs to be monitored and measured;
  - The methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
  - When the monitoring and measuring shall be performed;
  - When the results from monitoring and measurement shall be analyzed and evaluated.
- The performance and effectiveness of the QMS must be evaluated.
- Appropriate documented information must be retained as evidence of the results.

QUALITY

# 9.0 Performance Evaluation

## ISO 14001:2015 – 9.1 - Monitoring, Measurement, Analysis and Evaluation

### 9.1.1 General

- The organization must monitor, measure, analyze and evaluate its environmental performance by determining:
  - What needs to be monitored and measured;
  - The methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
  - The criteria against which the organization will evaluate its environmental performance, and appropriate indicators;
  - When the monitoring and measuring shall be performed;
  - When the results from monitoring and measurement shall be analyzed and evaluated.

# 9.0 Performance Evaluation

## ISO 14001:2015 – 9.1 - Monitoring, Measurement, Analysis and Evaluation

### 9.1.1 General *Continued...*

- Calibrated or verified monitoring and measurement equipment must be used and maintained.
- Environmental performance and the effectiveness of the EMS must be evaluated.
- Relevant environmental performance information must be communicated both internally and externally, as identified by the communication processes and as required by compliance obligations.
- Documented information must be retained as evidence of the monitoring, measurement, analysis and evaluation results.

# 9.0 Performance Evaluation

## ISO 45001: 2018 – 9.1 Monitoring, measurement, analysis and performance evaluation

### 9.1.1 General

The organization shall establish, implement and maintain processes for monitoring, measurement, analysis and performance evaluation.

The organization shall determine:

- a) what needs to be monitored and measured, including:
  - Extent to which legal requirements and other requirements are fulfilled;
  - Activities and operations related to hazards, risks and opportunities;
  - Progress towards achievement of the organization's OH&S objectives;
  - Effectiveness of operational and other controls;
- b) the methods for monitoring, measurement, analysis and performance evaluation, as applicable, to ensure valid results;
- c) the criteria against which the organization will evaluate its OH&S performance;
- d) when the monitoring and measuring shall be performed;
- e) when the results from monitoring and measurement shall be analyzed, evaluated and communicated.



# 9.0 Performance Evaluation

## ISO 45001: 2018 – 9.1 Monitoring, measurement, analysis and performance evaluation

### 9.1.1 General

- The organization must evaluate the OH&S performance, and determine the effectiveness of the OH&S management system.
- The organization ensures that monitoring and measurement equipment is calibrated or verified as applicable, and is used and maintained as appropriate.

*NOTE: There can be legal requirements or other requirements (e.g. national or international standards) concerning the calibration or verification of monitoring and measuring equipment.*

The organization shall retain appropriate documented information:

- as evidence of the results of monitoring, measurement, analysis and performance evaluation;
- on the maintenance, calibration or verification of measurement of equipment

# 9.0 Performance Evaluation

## ISO 9001:2015 – 9.1 - Monitoring, Measurement, Analysis and Evaluation

### 9.1.2 Customer Satisfaction

- The organization must monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled.
- The organization must determine the methods for obtaining, monitoring and reviewing this information.

Note: Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.

**Neither ISO 14001:2015 nor ISO 45001: 2018 share this requirement**

# 9.0 Performance Evaluation

## ISO 14001:2015 – 9.1 - Monitoring, Measurement, Analysis and Evaluation

### 9.1.2 Evaluation of Compliance

- Processes needed to evaluate fulfillment of compliance obligations must be established, implemented and maintained.
- The organization must:
  - Determine the frequency that compliance will be evaluated;
  - Evaluate compliance and take action if needed;
  - Maintain knowledge and understanding of its compliance status.
- Documented information must be retained as evidence of the compliance evaluation results.

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# 9.0 Performance Evaluation

## ISO 45001: 2018– 9.1 - Monitoring, Measurement, Analysis and Evaluation

### 9.1.2 Evaluation of compliance

The organization shall establish, implement and maintain a process for evaluating compliance with legal requirements and other requirements (6.1.3).

The organization shall:

- Determine the frequency and method(s) for the evaluation of compliance; evaluate compliance;
- Take action if needed (see 10.1);
- Maintain knowledge and understanding of its compliance status with legal requirements and other requirements;
- Retain documented information of the compliance evaluation result(s).

# 9.0 Performance Evaluation

## ISO 9001:2015 – 9.1 - Monitoring, Measurement, Analysis and Evaluation

### 9.1.3 Analysis and Evaluation

- Appropriate data and information arising from monitoring and measurement must be analyzed and evaluated.
- Such analysis must be used to evaluate:
  - Conformity of products and services;
  - The degree of customer satisfaction;
  - The performance and effectiveness of the QMS;
  - If planning has been implemented correctly;
  - The effectiveness of actions taken to address risks and opportunities;
  - The performance of external providers;
  - The need for improvements to the QMS.

Note: Methods to analyze data can include statistical techniques.

# 9.0 Performance Evaluation

## ISO 9001:2015 – 9.2 - Internal Audit

- **9.2.1:** Internal audits must be conducted at planned intervals to provide information on whether the QMS:
  - Conforms to:
    - 1) The organization's own QMS requirements;
    - 2) The requirements of ISO 9001:2015
  - Is effectively implemented and maintained.

## ISO 14001:2015 – 9.2 - Internal Audit

### 9.2.1 General

- Internal audits must be conducted at planned intervals to determine whether the EMS:
  - Conforms to:
    - 1) The organization's own EMS requirements;
    - 2) The requirements of ISO 14001:2015
  - Is effectively implemented and maintained.



# 9.0 Performance Evaluation

## ISO 45001: 2018 – 9.2 Internal Audit

### 9.2.1 General

The organization shall conduct internal audits at planned intervals to provide information on whether the OH&S management system:

a) conforms to:

- Organization's own requirements for its OH&S management system, including the OH&S policy and OH&S objectives;
- Requirements of this International Standard document;

b) is effectively implemented and maintained.

# 9.0 Performance Evaluation

## ISO 9001:2015 – 9.2 Internal Audit

- **9.2.2:** The organization must:
  - Plan, establish, implement and maintain an audit program including frequency, methods, responsibilities, planning requirements and reporting, which must take into account the importance of the processes concerned, changes affecting the organization, and the results of previous audits;
  - Define the audit criteria and scope for each audit;
  - Select auditors and conduct audits that ensure objectivity and the impartiality of the audit process;
  - Ensure that the results of the audits are reported to relevant management;
  - Take appropriate correction and corrective actions without undue delay;
  - Retain documented information as evidence of the implementation of the audit program and audit results.

Note: See ISO 19011 for guidance.

# 9.0 Performance Evaluation

## ISO 14001:2015 – 9.2 - Internal Audit

### 9.2.2 Internal Audit Program

- Implement and maintain an internal audit program including the frequency, methods, responsibilities, planning requirements and reporting of its internal audits.
- When establishing the internal audit program, the organization must take into consideration the environmental importance of the processes concerned, changes affecting the organization, and the results of previous audits.
- The organization must:
  - Define the audit criteria and scope for each audit;
  - Select auditors and conduct audits ensuring objectivity and the impartiality of the audit process;
  - Ensure that the results of the audits are reported to relevant management.
- Documented information must be retained for the audit program and the audit results.

# 9.0 Performance Evaluation

## ISO/DIS 45001.2 – 9.2 Internal Audit

### 9.2.2 Internal audit program

The organization, shall:

- Plan, establish, implement and maintain an audit programs including frequency, methods, responsibilities, consultation, planning requirements and reporting.
  - These must take into consideration the importance of the processes concerned and the results of previous audits
- Define the audit criteria and scope for each audit;
- Select competent auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
- Ensure that the results of the audits are reported to relevant managers; ensure that relevant audit results are reported to workers, and where they exist, workers' representatives, and other relevant interested parties;

# 9.0 Performance Evaluation

## ISO/DIS 45001.2 – 9.2 Internal Audit

### 9.2.2 Internal audit program

The organization, shall:

- Take action to address nonconformities and continually improve its OH&S performance (Clause10)
- f) retain documented information as evidence of the implementation of the audit program and the audit results.

***NOTE: For more information on auditing, refer to ISO 19011 Guidelines for auditing management systems.***

# 9.0 Performance Evaluation

## ISO 9001:2015 – 9.3 - Management Review

### 9.3.1 General

- Top management must review the QMS at planned intervals to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.

QUALITY





# 9.0 Performance Evaluation

## ISO 9001:2015 – 9.3 - Management Review

### 9.3.2 Management Review Inputs

- Management review must be planned and carried out taking into consideration:
  - Status of actions from previous management reviews;
  - Changes in external and internal issues that are relevant to the QMS;
  - Information on the performance and effectiveness of the QMS, including trends in:
    - 1) customer satisfaction and feedback from interested parties;
    - 2) the extent to which quality objectives have been met;
    - 3) process performance and conformity of products and services;
    - 4) nonconformities and corrective actions;
    - 5) monitoring and measurement results;
    - 6) audit results;
    - 7) the performance of external providers;
  - Adequacy of resources;
  - Effectiveness of actions taken to address risks and opportunities;
  - Opportunities for improvement.

# 9.0 Performance Evaluation

## ISO 9001:2015 – 9.3 - Management Review

### 9.3.3 Management Review Outputs

- The outputs of the management review must include decisions and actions related to:
  - Opportunities for improvement;
  - Any need for changes to the QMS;
  - Resource needs.
- Documented information must be retained as evidence of the results of management reviews.

QUALITY

# 9.0 Performance Evaluation

## ISO 14001:2015 – 9.3 Management Review

- Top management must review the EMS at planned intervals to ensure its continuing suitability, adequacy, and effectiveness.
- Management review must consider:
  - Status of actions from previous management reviews;
  - Changes in:
    - 1) external and internal issues that are relevant to the EMS;
    - 2) needs and expectations of interested parties, including compliance obligations;
    - 3) significant environmental aspects;
    - 4) risks and opportunities;
  - Extent to which environmental objectives have been achieved;
  - Environmental performance, including trends in:
    - 1) nonconformities and corrective actions;
    - 2) monitoring and measurement results;
    - 3) fulfillment of its compliance obligations;
    - 4) audit results;
  - Adequacy of resources;
  - Communications from interested parties, including complaints;
  - Opportunities for continual improvement.

# 9.0 Performance Evaluation

## ISO 14001:2015 – 9.3 Management Review

- Outputs of management review must include:
  - Conclusions on the continuing suitability, adequacy and effectiveness of the EMS;
  - Decisions related to continual improvement opportunities;
  - Decisions related to any need for changes to the EMS, including resources;
  - Actions, if needed, when environmental objectives have not been achieved;
  - Opportunities to improve integration of the EMS with other business processes, if needed;
  - Any implications for the strategic direction of the organization.
- Documented information must be retained as evidence of the results of management reviews.

QUALITY

# 9.0 Performance Evaluation

## ISO 45001: 2018 – 9.3 - Management Review

### 9.3 Management review

Top management shall review the organization's OH&S MS, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness.

The management review shall include consideration of:

- a) the status of actions from previous management reviews;
- b) changes in external and internal issues that are relevant to the OH & S management system including:
  - Needs and expectations of interested parties;
  - Legal requirements and other requirements;
  - Organization's risks and opportunities;
- c) the extent to which the OH&S policy and the OH&S objectives have been met;

# 9.0 Performance Evaluation

## ISO 45001: 2018 – 9.3 - Management Review

### 9.3 Management review

The management review shall include consideration of:

d) Information on the OH&S performance, including trends in:

- 1) incidents, nonconformities corrective actions and continual improvement;
  - Monitoring and measurement results;
  - Results of evaluation of compliance with legal requirements and other requirements;
  - Audit results;
  - Consultation and participation of workers;
  - Risks and opportunities;

e) adequacy of resources for maintaining an effective OH&S MS

f) relevant communication(s) with interested parties

g) opportunities for continual improvement.



# 9.0 Performance Evaluation

## ISO 45001: 2018 – 9.3 - Management Review

### 9.3 Management review

The outputs of the management review shall include decisions related to:

- Continuing suitability, adequacy and effectiveness of the OH&S management system in achieving its intended outcomes;
  - Continual improvement opportunities
  - Any need for changes to the OH&S management system,
  - Resources needed;
  - Actions if needed;
  - Opportunities to improve integration of the OH&S MS with other business processes;
  - Any implications for the strategic direction of the organization.
- The top management must communicate the relevant outputs of management reviews to its workers, and where they exist, workers' representatives (7.4.)
  - The organization must retain documented information as evidence of the results of management reviews.

# 10. IMPROVEMENT

QUALITY



# 10.0 Improvement

<b>ISO 9001:2015</b>	<b>ISO 14004:2015</b>	<b>ISO 45001: 2018</b>
10.1 (Improvement) General	10.1 (Improvement) General	10.1 (Improvement) General
10.2 Nonconformity and Corrective Action	10.2 Nonconformity and Corrective Action	10.2 Incident, Nonconformity and Corrective Action
10.3 Continual Improvement	10.3 Continual Improvement	10.3 Continual Improvement

QUALITY



# 10.0 Improvement

## ISO 9001:2015 – 10.0 -Improvement

### 10.1 General

- The organization must determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction, which must include:
  - Improving products and services to meet requirements as well as to address future needs and expectations;
  - Correcting, preventing, or reducing undesired effects;
  - Improving the performance and effectiveness of the QMS.

Note: Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.

## ISO 14001:2015 – 10.0 - Improvement

### 10.1 General

- The organization must determine opportunities for improvement (see [9.1](#), [9.2](#) and [9.3](#)) and implement necessary actions to achieve the intended outcomes of its EMS.

# 10.0 Improvement

## ISO 14001:2015 – 10.0 - Improvement

### 10.1 General

- The organization must determine opportunities for improvement (see **9.1**, **9.2** and **9.3**) and implement necessary actions to achieve the intended outcomes of its EMS.

## ISO 45001: 2018 – 10.0 - Improvement

### 10.1 General

- The organization shall determine opportunities for improvement ( 9.1, 9.2 and 9.3) and implement necessary actions to achieve the intended outcomes of its OH&S management system.

# 10.0 Improvement

## ISO 9001:2015 – 10.2 Nonconformity and Corrective Action

- **10.2.1:** When a nonconformity occurs, including any arising from complaints, the organization must:
  - React to the nonconformity and, as applicable:
    - Take action to control and correct it;
    - Deal with the consequences;
  - Evaluate the need for action to eliminate the cause of the nonconformity so that it does not recur or occur elsewhere by:
    - 1) reviewing and analyzing the nonconformity;
    - 2) determining the causes of the nonconformity;
    - 3) determining if similar nonconformities exist, or could potentially occur;
  - Implement any action needed;
  - Review the effectiveness of any corrective actions taken;
  - Update risks and opportunities determined during planning, if necessary;
  - Make changes to the QMS, if necessary.
- Corrective actions must be appropriate to the effects of the nonconformities encountered.



# 10.0 Improvement

## ISO 9001:2015 – 10.2 Nonconformity and Corrective Action

- **10.2.2** Documented evidence must be retained as evidence of:
  - The nature of the nonconformities and any subsequent actions taken;
  - The results of any corrective action.

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# 10.0 Improvement

## ISO 14001:2015 – 10.2 Nonconformity and Corrective Action

- When a nonconformity occurs the organization must:
  - React to the nonconformity and, as applicable:
    - 1) take action to control and correct it;
    - 2) deal with the consequences, including mitigating adverse environmental impacts;
  - Evaluate the need for action to eliminate the cause of the nonconformity so that it does not recur or occur elsewhere by:
    - 1) reviewing the nonconformity;
    - 2) determining the causes of the nonconformity;
    - 3) determining if similar nonconformities exist, or could potentially occur;
  - Implement any action needed;
  - Review the effectiveness of any corrective actions taken;
  - Make changes to the EMS, if necessary.
- Corrective actions must be appropriate to the effects of the nonconformities encountered, including .

# 10.0 Improvement

## ISO 14001:2015 – 10.2 Nonconformity and Corrective Action

- Corrective actions must be appropriate to the effects of the nonconformities encountered, including the environmental impacts.
- Documented evidence must be retained as evidence of:
  - The nature of the nonconformities and any subsequent actions taken;
  - The results of any corrective action.

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# 10.0 Improvement

## ISO 45001: 2018– 10.2 – Incident, Nonconformity and Corrective Action

- The organization shall establish, implement and maintain a process(es), that include(s) reporting, investigating and taking action, to determine and manage incidents, and nonconformities.
- When an incident or a nonconformity occurs, the organization shall:
  - React in a timely manner to the incident or nonconformity, and, as applicable:
    - Take action to control and correct it;
    - Deal with the consequences;
  - Evaluate, with the participation of workers (5.4) and the involvement of other relevant interested parties, the need for corrective action to eliminate the root cause(s) of the incident or nonconformity, in order that it does not recur or occur elsewhere, by:
    - Investigating the incident or reviewing the nonconformity;
    - Determining the cause(s) of the incident or nonconformity;
    - Determining if similar incidents have occurred, nonconformities exist, or if either could potentially occur;

# 10.0 Improvement

## ISO 45001: 2018– 10.2 – Incident, Nonconformity and Corrective Action

When an incident or a nonconformity occurs, the organization shall:

- Review existing assessments of OH&S risks and other risks, as appropriate (see 6.1);
- Determine and implement any action needed, including corrective action, in accordance with the hierarchy of controls (see 8.1.2) and the management of change (see 8.1.3);
- Assess OH&S risks prior to taking action that can result in new or changed hazards;
- Review the effectiveness of any action taken, including corrective action taken;
- Make changes to the OH&S management system, if necessary.

# 10.0 Improvement

## ISO 45001: 2018– 10.2 – Incident, Nonconformity and Corrective Action

- Corrective actions must be appropriate to the effects or potential effects of the incidents or nonconformities encountered.
- The organization must retain documented information as evidence of:
  - the nature of the incidents or nonconformities and any subsequent actions taken;
  - the results of any action and corrective action, including their effectiveness.
- The organization must communicate this documented information to relevant workers, and where they exist, workers' representatives, and relevant interested parties.

***NOTE The reporting and investigation of incidents without undue delay can enable hazards to be eliminated and associated OH&S risks to be minimized as soon as possible.***



# Continual Improvement

## ISO 9001:2015 – 10.3 Continual Improvement

- The organization must continually improve the suitability, adequacy and effectiveness of the QMS.
- The organization must consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that must be addressed as part of continual improvement.

## ISO 14001:2015 – 10.3 Continual Improvement

- The organization must continually improve the suitability, adequacy and effectiveness of the EMS to enhance environmental performance.

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# 10.0 Improvement

## ISO 45001: 2018– 10.3 – Continual Improvement

### 10.3 Continual improvement

The organization shall continually improve the suitability, adequacy and effectiveness of the OH&S management system, by:

- Enhancing OH&S performance;
- Promoting a culture that supports an OH&S management system.
- Promoting the participation of workers in implementation of actions for continual improvement of the OH&S management system.
- Communicating the relevant results of continual improvement to workers, and where they exist, workers' representatives.
- Maintaining and retaining documented information as evidence of the results of continual improvement.

# Chapter 3: IMS Requirements — What We Covered

## Learning Objectives

You should now be able to:

- List the requirements of the individual standards
- Integrate the requirements into a single IMS

## Chapter Agenda

- Context of the Organization
  - **Group Exercise 1 – Context**
  - **Group Exercise 2 – Assessing Risk**
- Leadership
- Planning
  - **Group Exercise 3 – Audit Scenarios**
- Support
- Operation
  - **Group Exercise 4 – Audit Scenarios**
- Performance Evaluation
- Improvement
  - **Group Exercise 5 – Audit Scenarios**

*Thank You!*

*Questions?*



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