

## **Training Session**

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The bottom half of the slide features a background image of a large, powerful ocean wave. The wave is dark blue and is curling over, creating a white, foamy crest. The sky above the wave is a clear, light blue. The text "Quality Standards" is overlaid on the right side of this image.

## **Quality Standards**

## Quality Standards

### Programme

1. Quality Standards
2. Operational Activities to be certified

# Quality Standards

## What is a standard?

A standard is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.



# Quality Standards

## What is ISO?

ISO (International Organization for Standardization) is the world's largest developer of voluntary International Standards. International Standards give state of the art specifications for products, services and good practice, helping to make industry more efficient and effective. Developed through global consensus, they help to break down barriers to international trade.

ISO have published more than 19 000 international standards covering almost all aspects of technology and business, from food safety to computers, and agriculture to healthcare.



# Quality Standards

## ISO 9000

### Quality management

The ISO 9000 Quality management family represents an international consensus on good quality management practices. It consists of standards and guidelines relating to quality management systems and related supporting standards.





# Quality Standards

## ISO 14000 Environmental management

The ISO 14000 family of standards addresses various aspects of environmental management including: labelling, performance evaluation, life cycle analysis, communication and auditing.



# Quality Standards

## ISO 31000 Risk management

ISO 31000 - Risk management sets out standards for the management of risks that are applicable to any type of organisation in the public or private sector.



# Quality Standards

## **ISO/IEC 17011:2004**

### **Conformity assessment -- General requirements for accreditation bodies accrediting conformity assessment bodies**

ISO/IEC 17011:2004 specifies general requirements for accreditation bodies assessing and accrediting conformity assessment bodies (CABs). It is also appropriate as a requirements document for the peer evaluation process for mutual recognition arrangements between accreditation bodies. Accreditation bodies operating in accordance with ISO/IEC 17011:2004 do not have to offer accreditation to all types of CABs. For the purposes of ISO/IEC 17011:2004, CABs are organizations providing the following conformity assessment services: testing, inspection, management system certification, personnel certification, product certification and, in the context of this document, calibration.





# Quality Standards

## **ISO/IEC 17020:2012**

### **Conformity assessment - Requirements for the operation of various types of bodies performing inspection**

ISO/IEC 17020:2012 specifies requirements for the competence of bodies performing inspection and for the impartiality and consistency of their inspection activities.



# Quality Standards

*ISO 9004 Managing for the sustained success of an organisation – A quality management approach.*

*ISO 10001:2007 Quality management – Customer satisfaction – Guidelines for codes of conduct for organisations*

*ISO 10002:2004 Quality management – Guidelines for complaints handling in organisations*

*ISO/TR 10013:2001 Guidelines for quality management system documentation*

*ISO 10015:1999 Quality Management – Guidelines for training*

*ISO 10019:2005 Guidelines for the selection of quality management system consultants and use of their services*

# Operational Activities to be Certified

## ISO 9001:2008 – Clause 4.1 General requirements (to a QMS)

The organisation shall:

- a. Determine the processes needed for the quality management system and their application throughout the organisation,
- b. determine the sequence and interaction of these processes,
- c. determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
- d. ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- e. monitor, measure where applicable, and analyse these processes, and
- f. implement actions necessary to achieve planned results and continual improvement of these processes.

# Operational Activities to be Certified

## ISO 9001:2008 – Clause 1.2 Application

Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the organisation's ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.



# Operational Activities to be Certified

Product realisation is the requirement that covers understanding and defining customer needs to providing the product or service to the customer.

It addresses these departments:

- Marketing
- Sales/order processing
- **Planning**
- Research & Development/Design
- **Procurement**
- Production/**Operations**/Manufacturing
- Installation
- Distribution
- Stores





# Operational Activities to be certified

## ISO 9001:2008 – Clause 4.1 – Note 2

An 'outsourced process' is a process that the organisation needs for its quality management system and which the organisation chooses to have performed by an external party.



# Operational Activities to be Certified

## ISO 9001:2008 – Clause 4.1 – Note 3

Ensuring control over outsourced processes does not absolve the organisation of the responsibility of conformity to all customer, statutory and regulatory requirements.

The type and extent of control to be applied to the outsourced process can be influenced by factors such as:

- a. The potential impact of the outsourced process on the organisation's capability to provide product that conforms to the requirements,
- b. The degree to which the control for the process is shared, and
- c. The capability of achieving the necessary control through the application of Clause 7.4 Purchasing.

## **Operational Activities to be Certified**

### **ISO 9001:2008 – Clause 7.4.1 Purchasing process**

**The organisation shall ensure that purchased product conforms to specified purchase requirements.**

**The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect on the purchased product on subsequent product realisation or the final product.**

## **Operational Activities to be Certified**

**ISO 9001:2008 – Clause 7.4.3 Verification of purchased product**

**The organisation shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.**

# Operational Activities to be Certified

**EN ISO 9001:2008 Quality Management Systems - Requirements**  
**Paragraph 7.5.2 – Validation of processes for production and service provision**

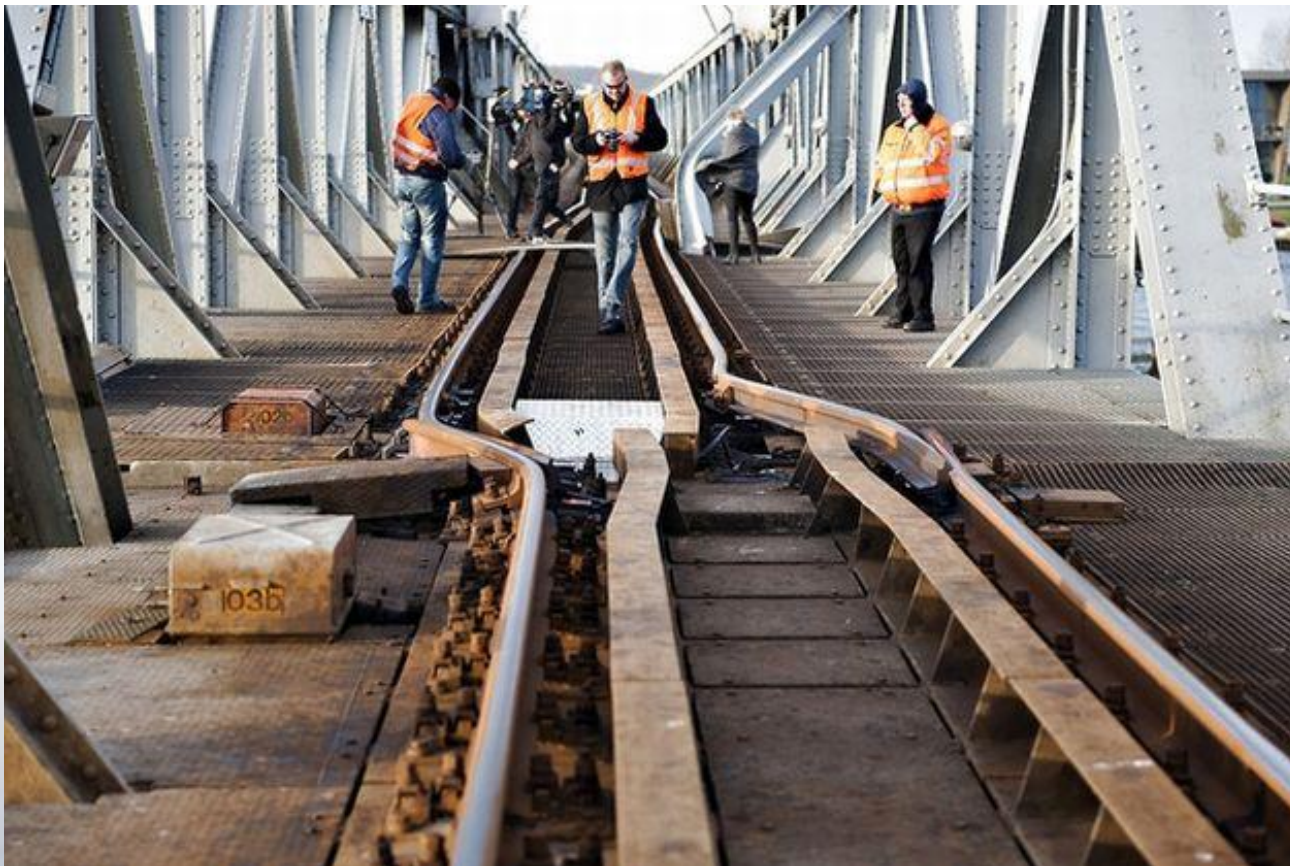
The organisation shall validate any process for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results. The organisation shall establish arrangements for these processes including, as applicable:

- a) Defined criteria for review and approval of the processes;
- b) Approval of equipment and qualification of personnel;
- c) Use of specific methods and procedures;
- d) Requirements for records; and
- e) Revalidation.



# Operational Activities to be Certified



# Questions?

