ISO 9001:2015 & ISO 14001:2015

Morning Briefing

'Significant Changes'

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ISO Management systems
What are they? Why use them?

- Complying with ISO management standards:
  - increases confidence in business relationships,
  - broadens opportunities
  - satisfies many legal and contractual requirements
  - provide an international benchmark

ISO High level text – Annex SL
What is it? Why has it been introduced?

- Developed by ISO
- Introduces common clause headings & core text
- Increases alignment and makes it easier to implement multiple management systems
- Recognises that no two organizations operate in the same way – greater flexibility
- ISO 9001, 14001, 27001, 55001, 45001, 22301 all adopting this structure

Key Changes

- Emphasis on the context of the organization
- Application of risk based thinking
- Increased involvement and accountability of top management
- Integration of the management system into overall business strategy & systems
- Greater emphasis on the customer and communications
- Less bureaucracy

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ISO 9001:2015 Significant Changes

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Main Changes

- High Level Structure (HLS)
- Context Of the Organisation
- Process approach
- The emphasis on leadership
- The focus on Risk based thinking / risk management
- Documented information / fewer prescribed requirements
- Emphasis on objectives measurement and change
- Communication

High Level Structure

- Management system standards
- Annex SL
- New terminology and structure

ISO 9001:2015 Contents

1. **Scope**
2. **Normative references**
3. **Terms and definitions**
4. **Context of the organization**
   - Understanding the organization and its context
   - Understanding the needs and expectations of interested parties
   - Determining the scope Of QMS
   - Quality management system and its processes
5. **Leadership**
   - Leadership and commitment
   - Quality Policy
   - Organizational roles, responsibilities and authorities
6. **Planning**
   - Actions to address risks and opportunities
   - Quality objectives and planning to achieve them
   - Planning of changes
7. **Support**
   - Resources
     - Organizational knowledge
   - Competence
   - Awareness
   - Communication
   - **Documented information**
8. **Operation**
   - Operational planning and control
   - Requirements for products and services
   - Design and development of products and services
   - Control of externally provided processes, products and services
   - Production and service provision
     - Post Delivery, Control of change
   - Release of products and services
   - Control of nonconforming outputs
9. **Performance evaluation**
   - Monitoring, measurement, analysis and evaluation
   - Internal audit
   - Management review
10. **Improvement**
    - General
    - Nonconformity and corrective action
    - Continual improvement

Black: core MS requirements **Red: new MS requirements**
Green: ISO 9001 specific

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Context of the organisation

- New Requirement
- Internal and external Factors
- Interested parties
- Scope of the QMS - exclusions

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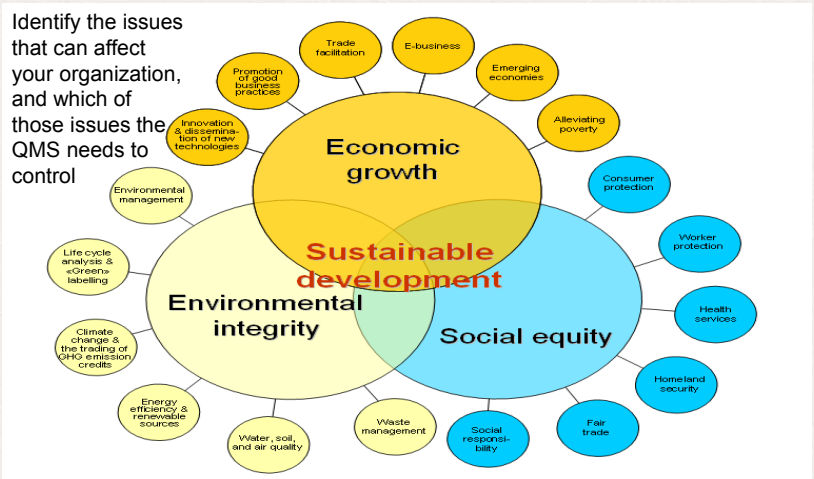
Clause 4 - Context of the organisation

Identify the issues that can affect your organization, and which of those issues the QMS needs to control



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Process Approach

- Promotes process approach
- Inputs and outputs
- Sequence and interaction
- Monitoring and measurement

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Assembly Process Model

A different example is shown below for an assembly process; this would be repeated for all the other processes in the organisation.

Assembly Process Owners
Position
Production Manager
Production Supervisors
Process Engineer

QMS Procedures / Documents	
QP08	Control of Non-Conformance
OP09	In process Inspection of Product
OP11	Packaging of Product
OP12	Scheduling
OP15	Assembly Work Instruction
CM01	Competency Matrix
	ETC.

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Assembly Process Model

From Process	Inputs		Outputs	To Process
QA Test	Quality Plan Records		Assembled Products	QA Test
Material Control	Materials		Quality Plan Records	QA Test
Product Engineering	Drawings	Assembly Process	Completed Control Charts	Data Analysis
Product Engineering	Machine Programs		Non-conforming products	Rework & Repair
Order Review & Scheduling	Production Schedule			
Product Engineering	Control Charts			
Resource Management	Manpower			

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Assembly Process Model

Measurement	Target
First Pass Yield	≥ 98%
RMA	≤ 500 DPPM
Machine Utilisation	86%
On time delivery to customer	≤ 3 days
Absenteeism	3.5%

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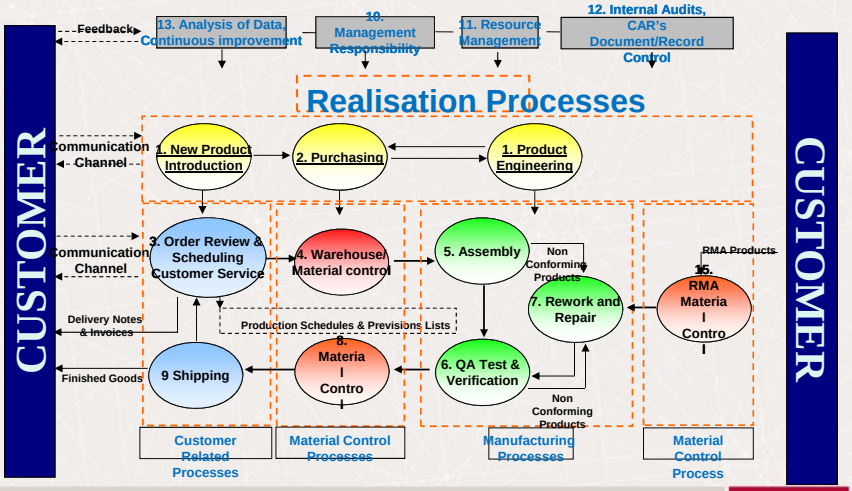
Process Interaction



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Leadership

- Emphasis on leadership
- Top management
- QMS responsibilities and authorities

Risk-based thinking

- Determine key issues & requirements that can pose adverse or beneficial effects to your organisation
- Address Risks and Opportunities
- Plan actions to mitigate risks and leverage opportunities
- Formal Risk Assessment methodology is not required

Documented information

- New terminology
  - replaces documentation, documents and records
- Fewer prescribed requirements
  - Plus any documents or records the organization deems necessary, including that of external origin
- Maintained or retained
- Flexibility on type of documents

Objectives measurement and change

- More emphasis on objectives
- Objective planning
- More emphasis on monitoring and measurement
- More emphasis on controlling changes

Communication

- Establish a communication process – Covering what, when, with whom and how it will communicate, internally & externally
- Information needs to be consistent & reliable
- Enable input/feedback for continual improvement
- Communicate externally as required by its compliance obligations and its communication process
- Respond to inquiries by external interested parties
- Retain records, *as appropriate*

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Benefits

- Provides an integrated approach to organisational management systems.
- Uses simplified language and a common structure and terms, which are particularly helpful to organizations using multiple management systems, such as those for the environment, health & safety, or business continuity
- Enhances an organisations ability to satisfy its customers, better quality management helps you meet customer needs.
- Puts greater emphasis on leadership engagement
- Helps address organizational risks and opportunities in a structured manner
- Is more user-friendly for service and knowledge-based organizations

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Thank you

Questions later

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ISO 14001:2015 Significant Changes

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Main Changes

- High Level Structure (HLS)
- Context of the organisation
- Risk based approach
- The emphasis on leadership
- Environmental compliance
- Continual Improvement
- Life cycle perspective
- Documented information
- Improved Communication

Provide a systematic approach that contributes to the 'environmental pillar' of sustainability

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High Level Structure

- Management system standards
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   - Understanding the organization and its context
   - Understanding the needs and expectations of interested parties
   - Determining the scope of the environmental management system
   - Environmental management system
5. **Leadership**
   - Leadership and commitment
   - Environmental policy
   - Organizational roles, responsibilities and authorities
6. **Planning**
   - Actions to address risks and opportunities
     - General
     - Environmental aspects
     - Compliance obligations
     - Planning action
   - Environmental objectives and planning to achieve them
     - Environmental objectives
     - Planning actions to achieve environmental objectives
7. **Support**
   - Resources
   - Competence
   - Awareness
   - Communication
     - General
     - Internal communication
     - External communication
   - Documented information
8. **Operation**
   - Operational planning and control
   - Emergency preparedness and response
9. **Performance evaluation**
   - Monitoring, measurement, analysis and evaluation
     - General
     - Evaluation of compliance
   - Internal audit
   - Management review
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Green: ISO 14001 specific

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Context of the Organisation

- Integrating environmental issues into the strategic planning of the organisation
- Knowledge gained guides EMS planning
- Determine relevant interested parties
- Determine their relevant needs and expectations
- Determine which of these needs and expectations become the organization's 'requirements'

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Risk-based thinking

- Determine key issues & requirements that can pose adverse or beneficial effects to your organisation
- Address Risks and Opportunities
- Plan actions to mitigate risks and leverage opportunities
- Formal Risk Assessment methodology is not required

Continual Improvement

- Determine opportunities for improvement and implement actions to achieve intended outcomes
- Improve the suitability, adequacy and effectiveness of the environmental management system
- Focus - improving environmental performance
  - Reducing adverse environmental impacts or
  - Increasing beneficial impacts.

Leadership

- Emphasis on leadership
  - Role as Leaders is to inspire others
- Top management
- EMS responsibilities and authorities

Environmental Compliance

- New terminology referring to an organization's obligations
- The organization determines those it has to comply with and those it chooses to comply with
- Evaluate compliance
- Maintain knowledge and understanding of compliance status

Life cycle perspective

- Explicit in determining environmental aspects and operational controls
- Considers the environmental impacts that can be controlled and influenced during each stage of the product lifecycle
  - Design
  - Raw material acquisition
  - Manufacture
  - Packaging/Transport/Delivery
  - Use
  - End of life treatment & final disposal
- Life cycle perspective does not require a life cycle assessment

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Improved Communication

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Benefits

- Provides an integrated approach to organisational management systems. Aligns:-
  - Environmental management to business strategy
  - Environmental initiatives with business priorities
  - EMS processes with other management system
- Uses simplified language and a common structure and terms, which are particularly helpful to organizations using multiple management systems,
- Puts greater emphasis on leadership engagement
- Risk-based approach to protect the environment
  - Prevent adverse impacts
  - Pursue opportunities with beneficial impact & competitive advantage

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Benefits

- Optimize the product footprint
  - Address during product design
  - Focus on each lifecycle stage - raw materials, manufacture, transport, packaging, consumer use and final disposal
- Enhance environmental performance
- Raise environmental awareness & involvement

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Thank you

Questions