

ISO 9001:2015 Revision Refresher

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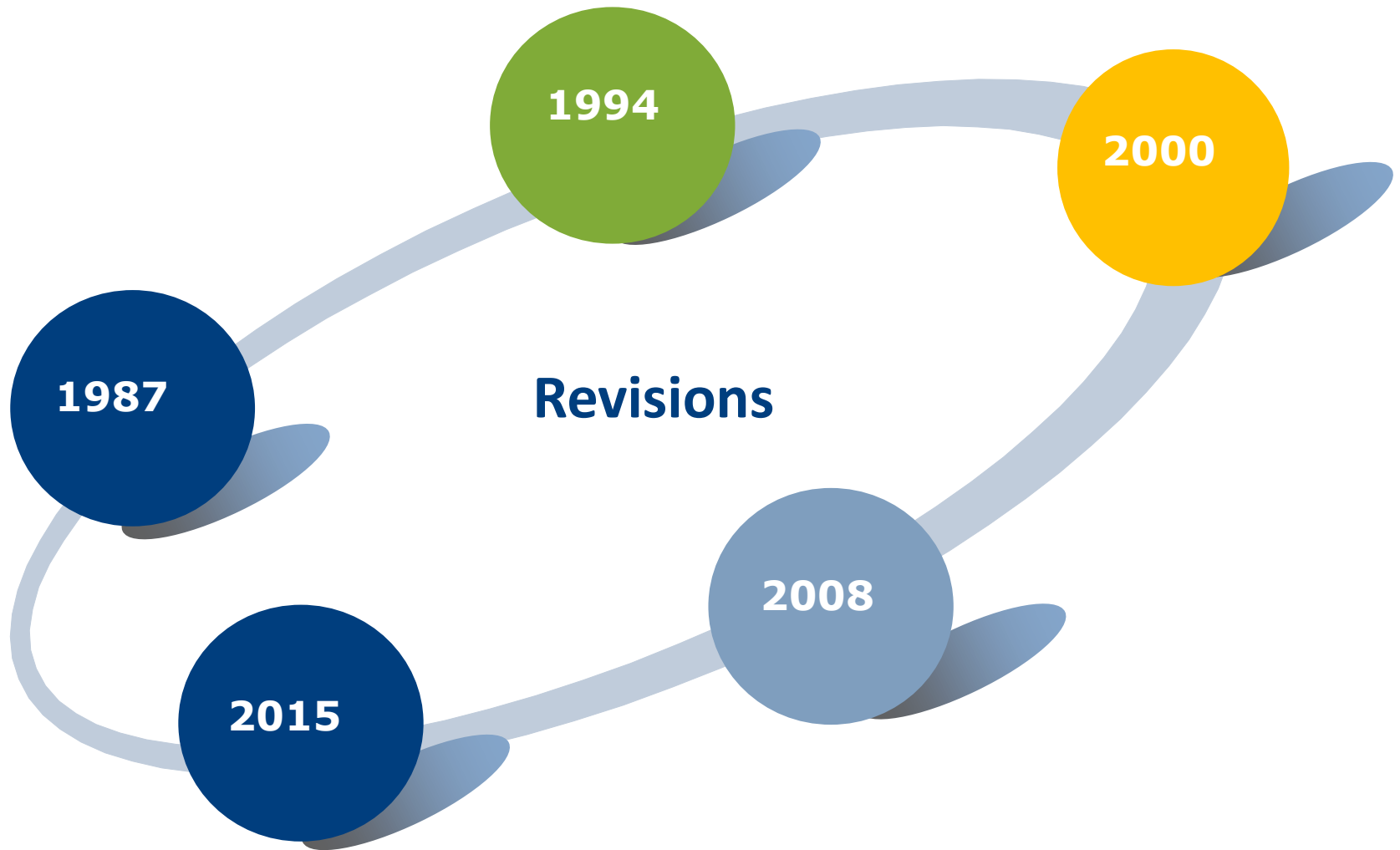


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ISO 9000 Background



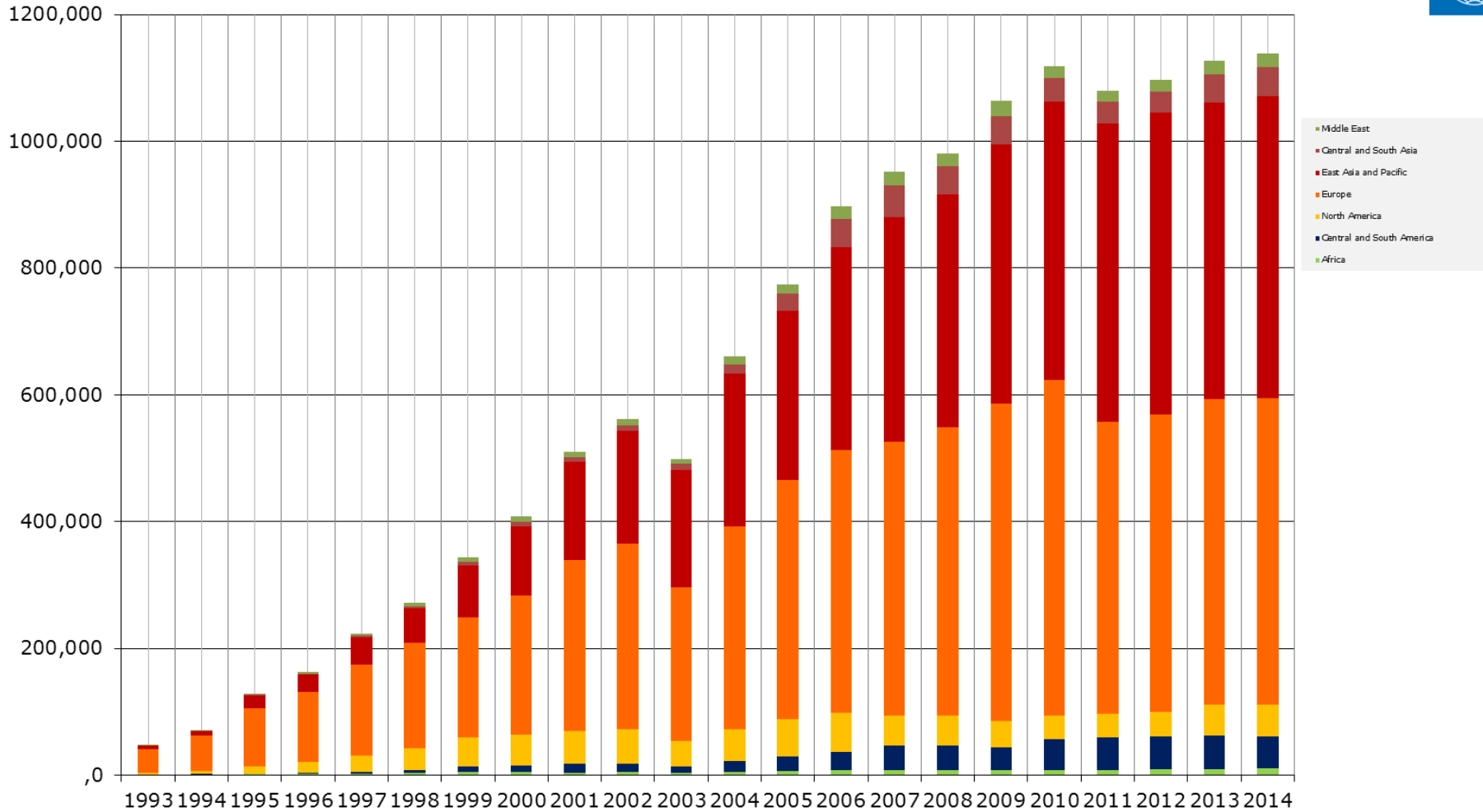


- **The last major revision took place in 2000;**
- **ISO 9001:2000** made a **radical change** in thinking;
- Similarly to **ISO 9001:2015**;
- The concept of **process management** placed at the heart of the standard;
- Continual **process improvement** and **customer satisfaction** were also made explicit.

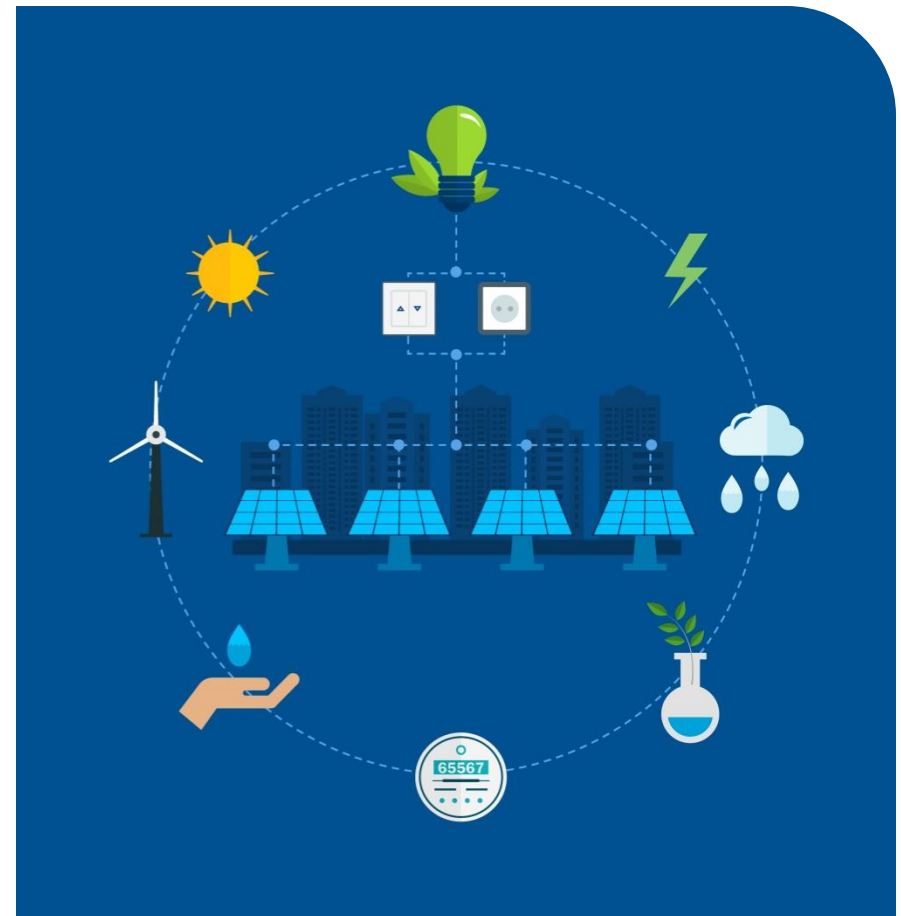
ISO 9001:2008 in Retrospect



ISO 9001 - Worldwide total



- Documentation requirements were the main focus;
- Mandatory documented procedures required are...numerous
- 'Process approach' is expected by the standard but not clearly defined so not understood in the business world
- Performance Monitoring. We now need to use all that wonderful data we have collected.



Key Changes



ISO 9001:2015 Key Changes in Concept & Philosophies

- Reinforced Process approach
- Risk-based thinking
- Flexibility in documenting the management system
- “Enhanced” stakeholder perspective
- Interested Parties and Boundaries now to be well understood
- Business metrics to fit our key processes.



Requirements set out in Sections 4-10

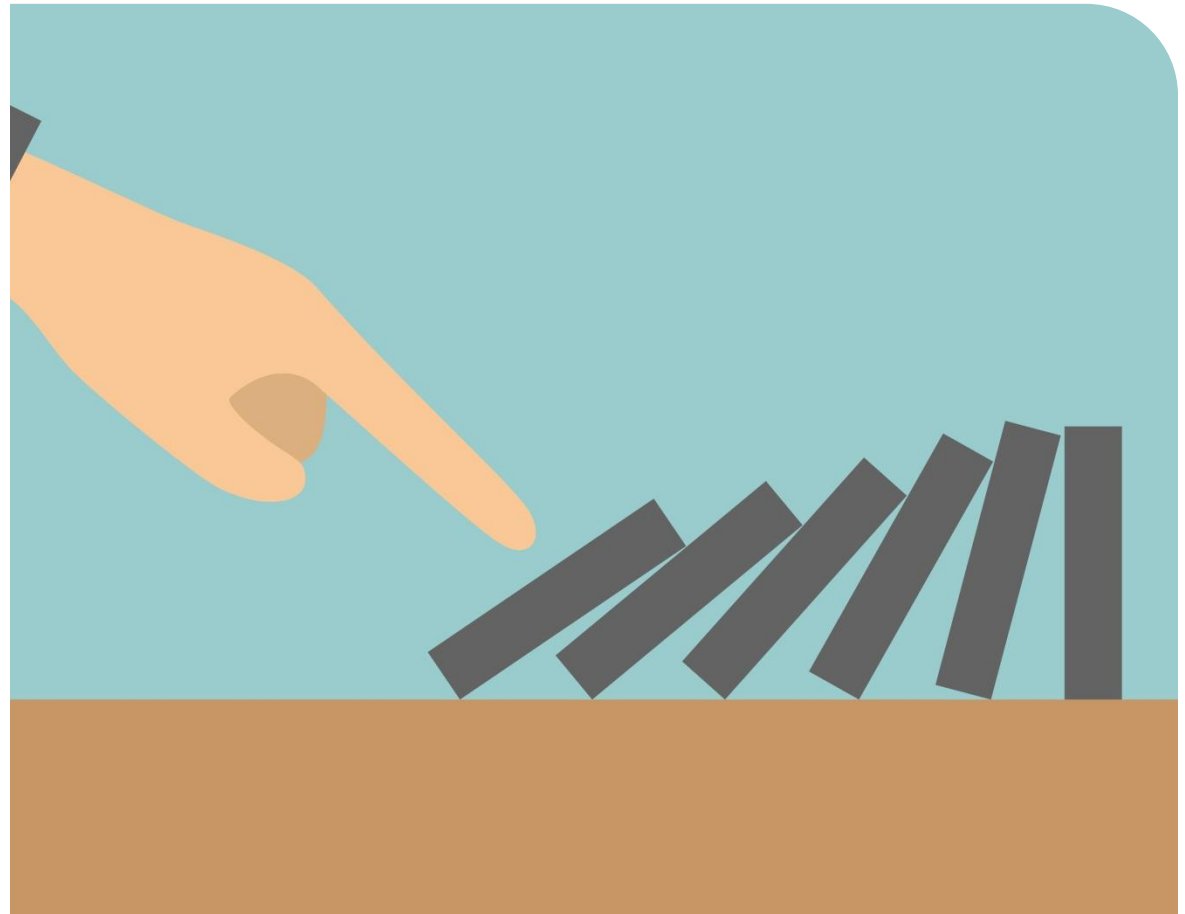
The business related standard follows the same cycle as plan do check and act.



<ul style="list-style-type: none">1. Scope2. Normative references3. Terms and references4. Context of the organization5. Leadership6. Planning	PLAN
<ul style="list-style-type: none">7. Support	DO
<ul style="list-style-type: none">8. Operation	CHECK
<ul style="list-style-type: none">9. Performance evaluation10. Improvement	ACT

- ISO 9001:2015 is based on **7 management principles**
- ***Mutually beneficial supplier relationships*** becomes ***Relationship Management***;
- ***Continual improvement*** becomes ***Improvement***
- ***Suppliers are Interested Parties***
- ***Process Approach-leadership driven. Not just the quality guy anymore. It is a business system run by management!***
- ***Risk base thinking***
 - It's commonplace in our jobs and daily lives (i.e. driving, visiting a city when abroad, hiring someone, making an investment, etc.);
 - External and internal risks endanger the achievement of goals and objectives...
 - For this reason the concept of risk and risk-based thinking go throughout the entire process approach (risk related requirements throughout the QMS standard).

The primary focus of a QMS is to meet customer requirements and to strive to exceed customer expectations;



- Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the objectives of the organization
- Leadership must take accountability for the effectiveness of the management systems.
- Leadership expectations have been raised with respect to participation and promotion on the systems.



- Clause 5 now entitled “Leadership”
- **Top management** is now required to take a **more active involvement** in the quality management system. Stronger emphasis on the overall accountability of top management for the effectiveness of the management system.
- The **figure of management representative no longer explicitly mentioned**. In the absence of specific requirement for a management representative, the organization may **choose a structure** of assigning responsibilities as appropriate to ensure relevant responsibilities and authorities are assigned.

ISO 9001:2015 also contains a new requirement aimed at ensuring that organizations take steps to capture and preserve knowledge and learning, which is necessary for the effective operation of their processes and for ensuring the conformity of their products and service.

The bar is now raised for demonstration of awareness.

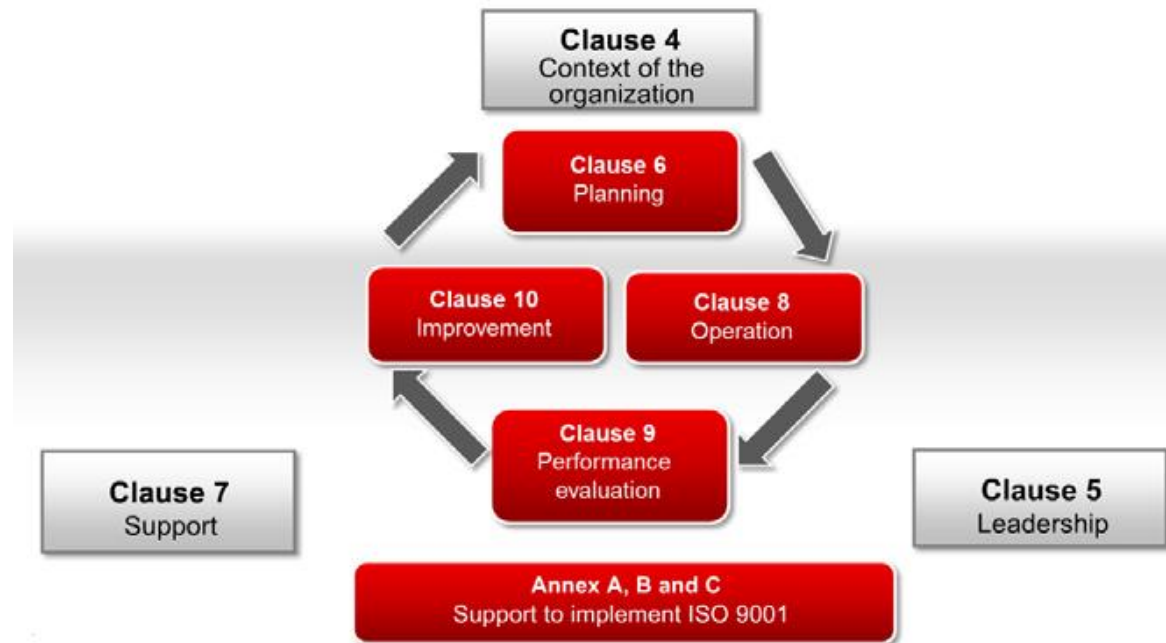


Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system.

Establishing, implementing, controlling and maintaining the processes in accordance with established criteria are required to meet management system requirements.



- Section 5.1.1 requires top management to make sure that QMS is integrated into business processes.
- The “process approach” is now more “explicit” in section 4.4



An example of a process which includes risks and regulatory requirements and associated customer requirements.

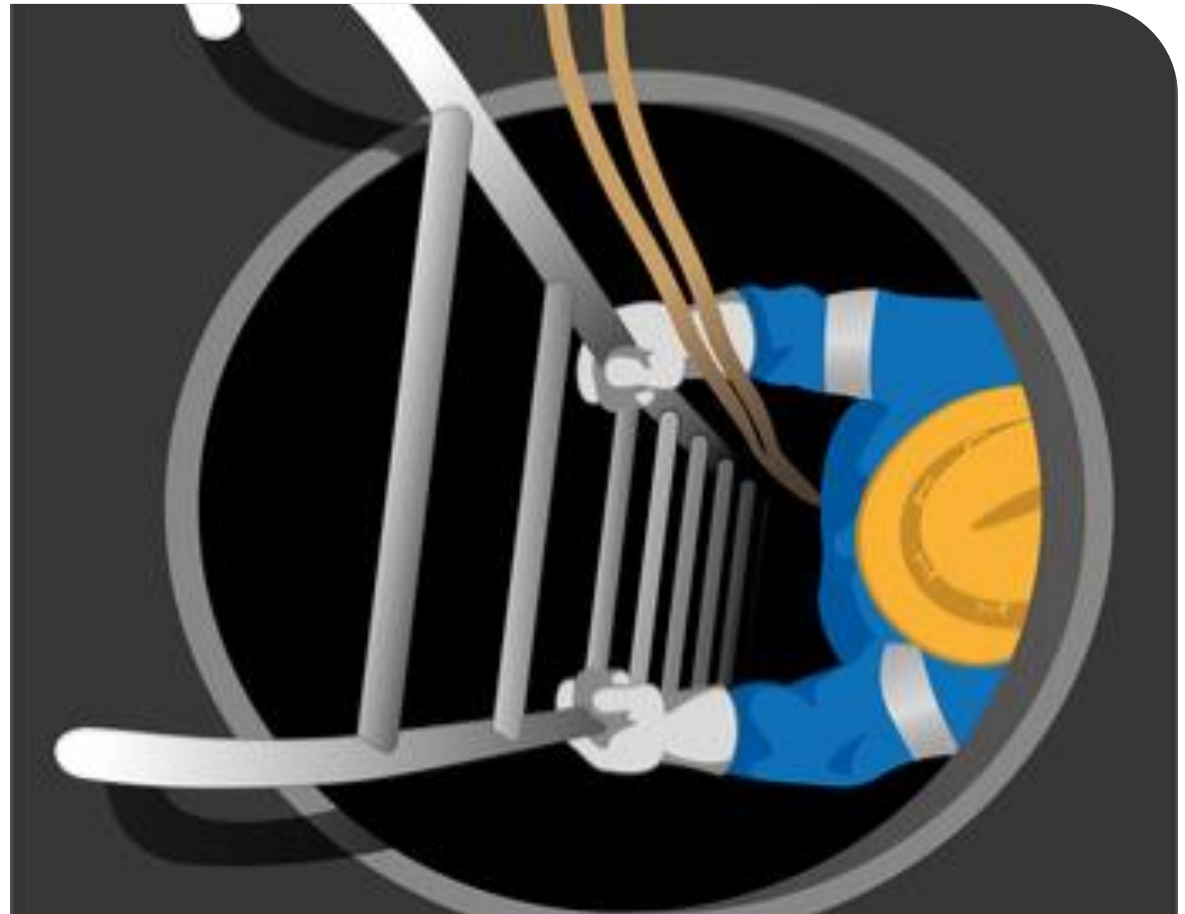
<p>Infrastructure- (process equipment, software and hardware, supporting services)</p>	<p>Process flow:</p>	<p>Human Resources-(education, knowledge, skills, training and experience)</p>
<p>Inputs:</p>	<p>Regulatory Requirements</p> <p>External and Internal Requirements impacting process</p>	<p>Outputs</p>
<p>Process Monitoring- (measurements, key performance indicators, trends, action plans for improvement, linkage to BP)</p>	<p>Risks associated with the process</p>	<p>Documentation-(process maps, procedures, standards, instructions, methods, forms):</p>

Successful organizations have an **ongoing focus on improvement.**”

Organizations need to review data analyze make decisions to continually improve

Cannot improve what you do not measure.

Sections 9 Performance Evaluation and 10 Improvement work hand in hand in improving an organization



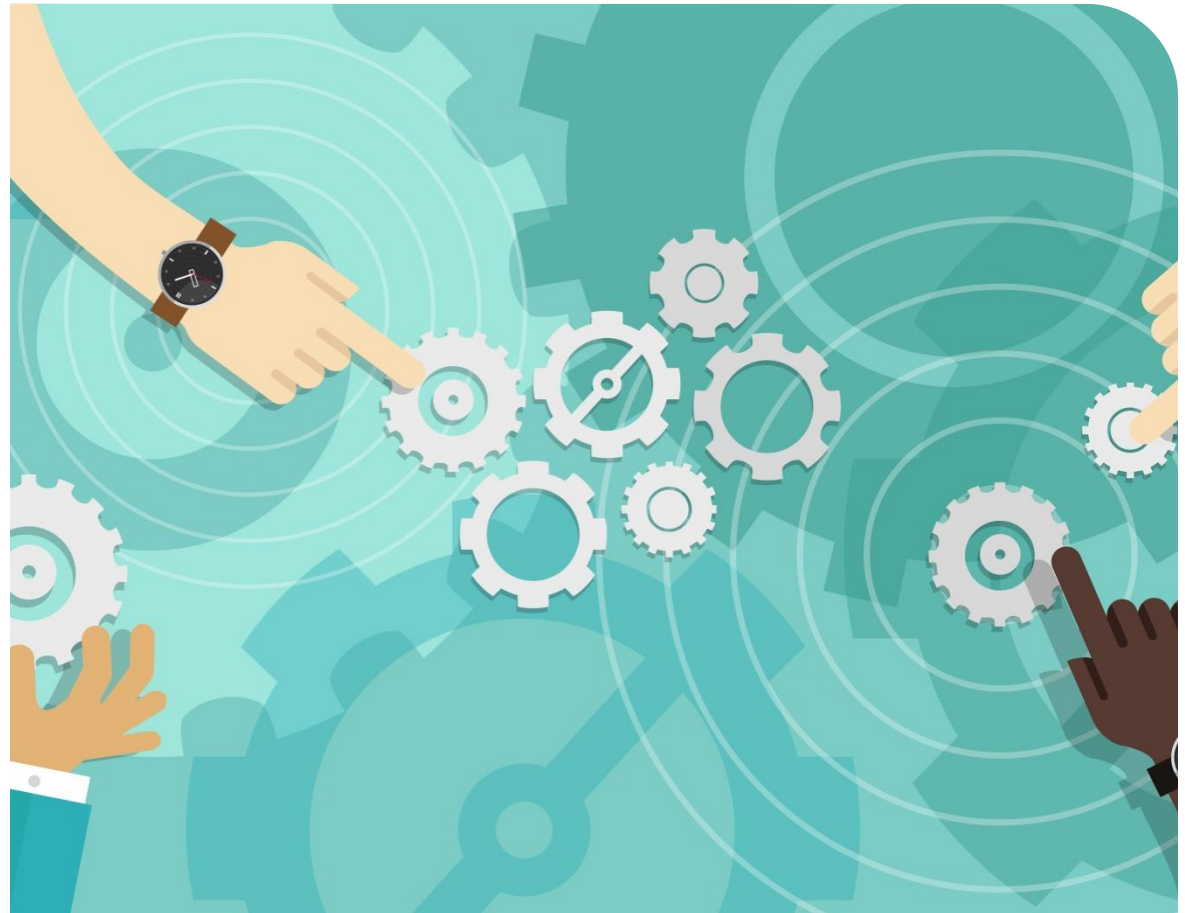
Section 9 Performance Evaluation

- Monitor measure and act
- Determine when and how often data is to be analyzed and evaluated to determine effectiveness
- Customer Satisfaction-determine how this is measured by the organization.
- Management Review, Internal Audit corrective action
- Note: Metrics should be two-fold.
- Effective metrics tell us if we are meeting the goal
- Efficient metrics tell us what it is costing to reach the goal
- BOTH ARE NEEDED



Section 10 Improvement

- Opportunities for improvement to be identified to enhance:
 - customer satisfaction
 - Products, services and future needs
 - Reducing undesired effects (risk mitigation)
- Corrective action-root cause and effective corrective action
- The organization shall continually improve the qms
- Determine as an output of management review the analysis of data and where action is needed to drive improvement



Decisions based on the analysis and evaluation of data and information are more likely to produce desired results.

More focus on evaluating trends and changes in QMS.



- **Preventive action** has been **removed** from ISO 9001:2015.
- Covered by the risk-based thinking concepts in the Planning section and other clauses of the standards.
- The standards themselves have become risk-based, preventive tools.



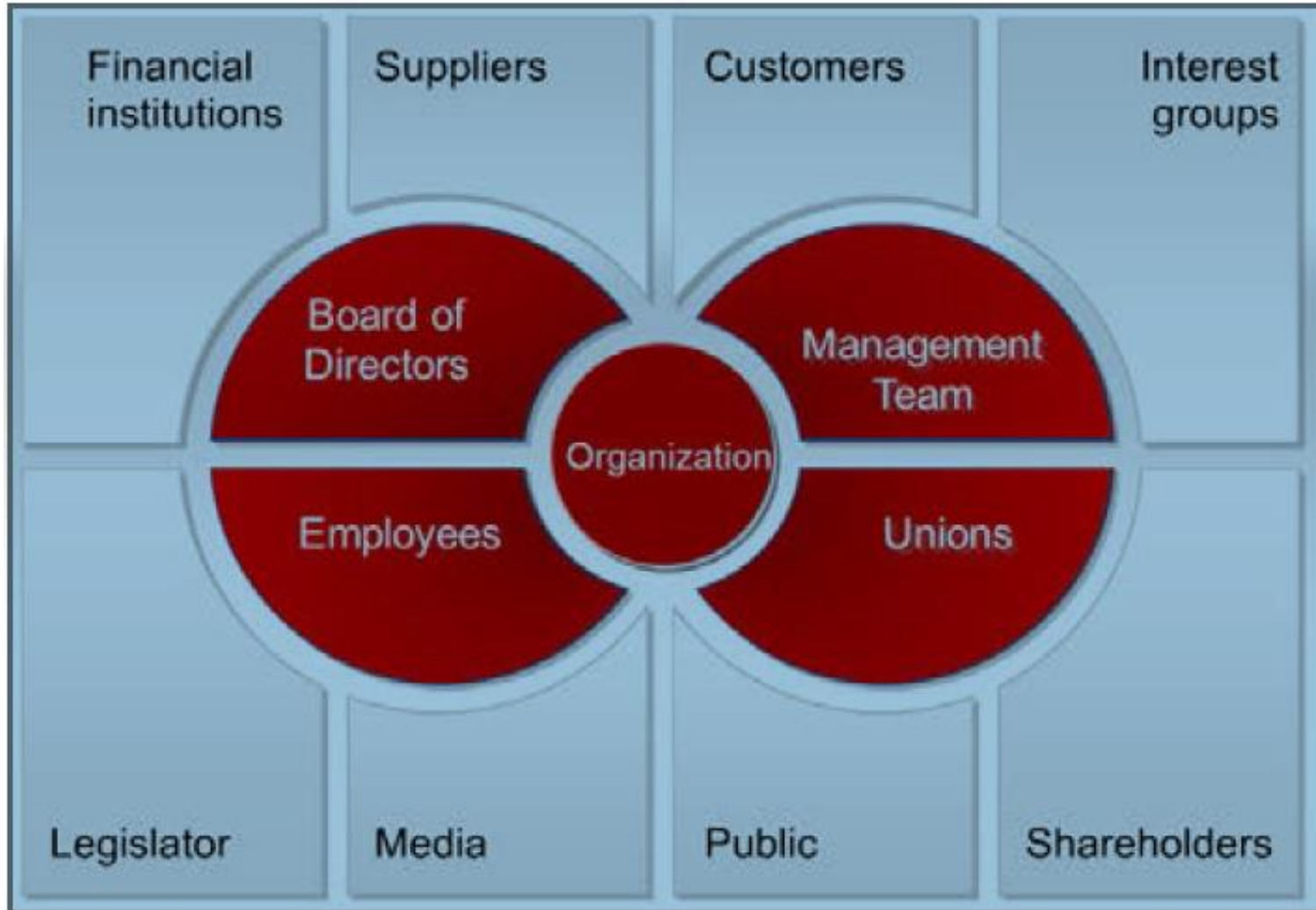
- Risk is often formulated as a combination of an event's consequences and likelihood of occurrence (and detection of precursors in some methodologies)
- Quantitative or qualitative approach, or a blend...
- ISO 9001:2015 requires a systematic approach to risk
- When selecting methodology the organization should consider the effects of failures, for example:
 - failing jet engine vs scratch on the exterior front of a washing machine...
 - Impacts of releases to the environment: onto the ground in an industrial park vs. air emissions upwind of a school.

- Certain risks can lead to a positive deviation and be seen as a opportunity...
- All risks managed adequately through the QMS/EMS represent an overall opportunity for the organization...
- Examples of a risk-based approach would be the FMEA (failure mode effects analysis).
- ***Key is risks are identified as required throughout the standard and actions taken to mitigate the risk and continually improve.***

For sustained success, organizations manage their relationships with interested parties, such as customers, suppliers, regulatory agencies, and communities.



Identification and analysis of interested parties



- A whole new clause 4 requires now the organization to consider it's purpose and its context, and to determine the scope of its management system;
- 4.1 Understanding the Organization and its Context and;
- 4.2 Understanding the Needs and Expectations of Interested Parties.
- Various well-established methodologies can be employed: SWOT, PEST, SOAR, Porter's 5 forces analysis, Value chain analysis

- ISO 9001:2015 has replaced “product” with “goods and services”;
- All products can actually be considered as a service or better, a solution to the customer (buying a smartphone, the customer is actually after the communication services...)
- “Purchasing” and “outsourcing” are now replaced by “externally provided products and services”. Clause 8.4 Control of Externally Provided Products and Services addresses all forms of external provision.
- The organization is required to take a risk-based approach to determine the type and extent of controls appropriate to each external provider and all externally provided products and services

- ISO 9001:2015 contains general requirements for **documented information**, with no required documented manual, documented procedures or records.
- **'Documented information'** now **replaces both documents and records**
- Document control and record control requirements no longer exist; however similar control requirements apply to the documented information.
- **No mandatory procedures** are required by the revised standards. More flexibility is afforded organization with respect to determining the extent of documented information needed to ensure processes are effectively controlled.

Mandatory documented information previously known as documents

1. Scope of the QMS (4.3)
2. Operation of processes (4.4)
3. Quality policy (5.2.2)
4. Control of product and service provision (8.5.1)

Mandatory documented information previously known as records

1. Operation of processes (4.4)
2. Quality objectives (6.2.1)
3. Monitoring and measurement resources (7.1.6)
4. Competence (7.2)
5. General (7.5.1)
6. Operational planning and control (8.1)
7. Requirements review (8.2.3)
8. Design and development planning (8.3.2)
8. Design and development (8.3.5)
9. Design and development changes (8.3.6)

10. Externally provided products and services (8.4.1)
11. Traceability (8.5.2)
12. Control of changes (8.5.6)
13. Release of products and services (8.6)
14. Control of nonconforming process outputs, products and services (8.7)
15. Monitoring, measurement, analysis and evaluation (9.1.1)
16. Internal audit (9.2)
17. Management review (9.3)
18. NC and corrective action (10.2)

What Companies Do Not Have to Do



- Organizations do not need to remove their management representatives. While there is no requirement in ISO 9001:2015 for a management representative, this does not prevent organizations from choosing to retain this role if they so wish. Be aware, however, that some of the duties traditionally assigned to the management representative by top management will need to be assumed directly by top management.
- Organizations do not need to throw out their Quality Manuals and Documented Procedures. While ISO 9001:2015 sets out no requirement for organizations to hold either a Quality Manual or Documented Procedures, if this documentation is in place, needed and working well, there is no need for it to be withdrawn.

- Organizations do not need to renumber existing documentation to correspond to the new clause references. Whether organizations choose to carry out a renumbering exercise may depend upon whether the benefits gained from renumbering will exceed the effort involved in making the changes. However, references need to be made in conformance with the standards.
- Organizations do not need to restructure their management systems to follow the sequence of requirements as set out in the ISO standards. Providing all of the requirements contained are met, the organization's system will be conformant. Again, however, there must be proper references to related processes.

- Organizations do not need to Refresh existing documentation to use the new terms and definitions contained within the ISO standards. Once again, organizations are free to make the judgment as to whether this effort would be worthwhile. If organizations are more comfortable using their own terminology, e.g. “records” instead of “documented information”, or “supplier” rather than “external provider” then this is perfectly acceptable

- The transition period for users of ISO 9001:2008 to transfer to ISO 9001:2015 is September 14, 2018. 3 years from the release date (September 23, 2015 for ISO 9001). All QMS certificates will expire three years from the release dates (2018)
- Aerospace and automotive both will adhere to the same September 14, 2018 expiring date.
- ISO 13485 did not align with the new 9001:2015 requirement
- Both TS and AS have released their versions containing 9001:2015

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