1. **Changes in ISO 9001 Requirements**

**2.1 New Structure**

All new Management System Standards of ISO are now based upon the same high level structure, requiring all requirements to align on the same set of frameworks. The new ISO 9001 revision is also based on this high level structure and follows Appendix SL to the ISO directives, Part 1. The basic clauses of ISO 9001 have increased from 8 to 10, but the model is still based on Plan-Do-Check-Act (PDCA) cycle.

A side by side comparison of the structural difference between ISO 9001:2008 and ISO 9001:2015 is given in the table below:

|  |  |
| --- | --- |
| **ISO 9001:2015** | **ISO 9001:2008** |
| Scope | Scope |
| Normative References | Normative References |
| Terms and Definitions | Terms and Definitions |
| Context of the Organization | Quality Management System |
| Leadership | Management Responsibility |
| Planning | Resource Management |
| Support | Product Realization |
| Operation | Measurement, Analysis and Improvement |
| Performance Evaluation |  |
| Improvement |  |
|  |  |

The aim of bringing all management system standards down to a common structure is to help organizations and businesses integrate their management system parts to attain a unified management system. This new Annex SL harmonization of the requirements between different management systems can simplify your life if you’re implementing multiple systems (e.g. ISO 9001 and 27001) in the same organization. For many that will be a huge win.

**2.2 Risk Management**

With every new revision of the standard, certified organizations are able to get more and more quality-focused with new concepts. Risk management is the most highlighted concept in 2015 revision that has been significantly mentioned time and again in the standard. Fundamental concepts like risk identification, risk qualification and risk management have been introduced to ensure that a product or service supplied to a client conforms to all requirements in the long run. Risk management also comes with the concepts of corrective and preventive actions. The former one corresponding to a mismanaged or unidentified risk while the latter meaning a risk related to a possible future noncompliance.

**2.3 Process Approach**

Section 0.3 of ISO 9001:2015 enforces the adaptation of process approach by organizations. This does not only mean to recognize workflows in a company but also to manage them in a specific manner. Process approach is a management strategy according to which managers consolidate organizational processes and control their interactions as well as their inputs and outputs which hold the processes together. For a quality management system, the process approach means a coherent and integrated process-based quality management system.

In a process based QMS, the output of one process is the input of the next one, and hence all processes are interrelated through their input-output relationship. This leads to a single integrated system of process based QMS.

To sum it up, process approach in ISO 9001:2015 calls for organizations to identify:

* Processes required for QMS
* Interaction and sequence of the processes
* Required inputs and possible outputs of each process
* Risks and opportunities for each process
* Roles and authorities assigned handle to each process
* Resources needed by each process
* Procedures to measure, manage, monitor, control and evaluate each process

**2.4 Roles and Responsibility**

ISO 9001:2015 revision has put off the concept of assigning a “management representative” to monitor the system. Rather the responsibility has been put on top management to enable them to responsibly demonstrate commitment and leadership towards organizational goals. The quality policy has to be in line with strategic goals and all QMS requirements have to be made a part of business processes.

The leadership should have a strong hold on organizational strengths and weaknesses to measure their ability to deliver quality. The concepts of business process management and risk management need to be applied, which will help to allocate responsibilities for every process and identify associated risks. The top management holds the responsibility to assign responsibility and authority for QMS tasks but it bears the final responsibility to account for the effectiveness of its quality management system.

A new stack of requirements listed in new clause 5.1.1 focus on the need for top management to demonstrate leadership and commitment to the quality management system. There are no less than 6 new requirements to be aware of, on top of the 5 that existed before. Three of the most important are the following:

1. Engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
2. Promoting continual improvement;
3. Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

In 5.1.1 (c) it is no longer sufficient for top management to establish the quality policy, they now have to ensure that it is communicated, understood and applied within the organization.

**2.5 Documentation**

ISO 9001:2008 classified documents as “documents” and “records”. Documents included process structure, policies, procedures, etc. whereas records included audit schedule, work history, etc. The 2015 revision has removed this specific requirement and documentation has been introduced with the concept of “documented information”. The documented information incorporates both documents and records. Documented information is important organizational data that requires to be maintained and controlled by the company.

**2.6 Organizational Context**

Context of the organization has been added as a new clause (Clause 4) into the standard and requires an understanding of why your organization exists and what purpose does it serve. It requires organizations to conduct context analysis, identification of stakeholders and to determine the QMS scope. This way, organizations are able to have a better understanding of issues that can have a positive or negative impact on their activities and management of responsibilities. Issues can be both internal and external, and include characteristics, conditions, or change of circumstances.

Stakeholders or “interested parties” need to be defined in detail, as they no longer include only customers. A complete knowledge of every interested party, its interests, and potential threats that they may pose to your organization must be maintained.

Furthermore, the last part of the clause requires you to focus your Quality Management System towards your key processes, which should be improved and developed continually according to changing circumstances.

Hence, Clause 4 comes with two big new changes:

* First a focus on understanding the organization and its context (clause 4.1).
* Second, a requirement to determine your Interested Parties and their relevant requirements.

What is the motivation for these changes?

For many years, detractors of ISO 9001 have been able to claim with some justification that an ISO management system – with its emphasis on documentation and auditing of processes and procedures – can bring the perverse effect of setting your processes in concrete.

The more we define and document your processes, adding structure and change control, the more effort people need to make to overcome organizational inertia to get these processes changed in the future. In a world that’s changing fast under the impact of new technologies and increased globalization, this can lead to a loss of competitiveness – not good!

By adding this new requirement to monitor and review the external and the internal environment, the architects of the standard are trying to provide a counter-measure against organizational rigidity. For most of us, it can be dealt with by copying and pasting the relevant sections from our most recent business plan.

The second change is the introduction of the term Interested Parties, a term that isn’t mentioned in any of the main clauses of the old standard. This makes explicit the need to serve the interests of a broader range of stakeholders, including employees and the local community, not just customers and the regulatory authorities that were mentioned in ISO 9001:2008.

The bottom line is that we now need to record who are our most important Interested Parties and their requirements, to avoid an entry into an auditor’s Non Conformance Report.