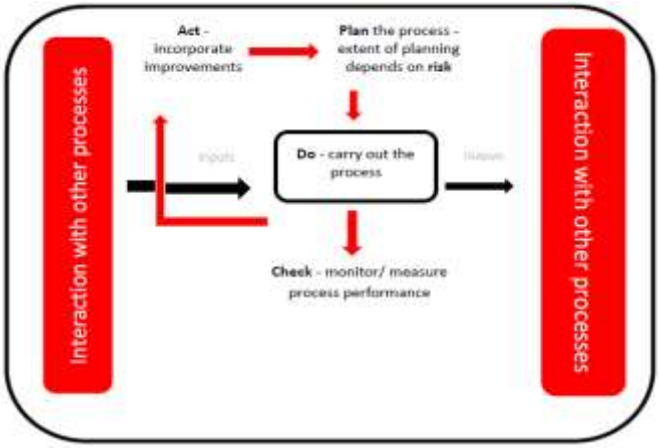
## Comparing the new version of ISO 9001:2015 with ISO 9001:2008

ISO 9001:2015 will be based on Annex SL – the new high level structure (HLS) that brings a common framework to all ISO management systems. This helps to keep consistency, align different management system standards, offer matching sub-clauses against the top-level structure and apply common language across all standards. With the new standard structure in place, organizations will find it easier to incorporate their quality management system into the core business processes and get more involvement from senior management. Based on Annex SL, Fig. 1 shows how the clauses of the new high level structure could also be applied to the Plan-Do-Check-Act cycle. The PDCA cycle can be applied to all processes and to the quality management system as a whole

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|---|---|
| **Context of the organization** | Consider the combination of internal and external factors and conditions that can have an effect on an organization's approach to its products, services and investments and interested parties |
| **Issues** | Issues can be internal or external, positive or negative and include conditions that either affect or are affected by the organization |
| **Interested parties** | Can be a person or organization that can affect, be affected by, or perceive themselves to be affected by a decision or activity. Examples include suppliers, customers or competitors. |
| **Leadership** | Requirements specific to top management who are defined as a person or group of people who directs and controls an organization at the highest level |
| **Risk associated with threats and opportunities** | Refined planning process replaces preventive action.and is defined as the 'effect of uncertainty on an expected result |
| **Communication** | There are explicit and more detailed requirements for both internal and external communications |
| **Documented information** | Replaces documents and records |
| **Performance evaluation** | The measurement of quality performance and the effectiveness of the QMS, covering the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results |
| **Nonconformity and corrective Action** | More detailed evaluation of both the nonconformities themselves and corrective actions required |
| **Management Review** | More detailed requirements relating to inputs and outputs of the review |

**Clause 4: Context of the organization**

This is a new clause that establishes the context for the QMS. Firstly, the organization will need to determine external and internal issues that are relevant to its purpose, i.e. what are the relevant issues, both inside and out, that have an impact on what the organization does, or that would affect its ability to achieve the intended outcome(s) of its management system. It should be noted that the term 'issue' covers not only problems which would have been the subject of preventive action in previous standards, but also important topics for the management system to address, such as any market assurance and governance goals that the organization might set. The final requirement in clause 4 is to establish, implement, maintain and continually improve the QMS in accordance with the requirements the standard.

**Clause 5: Leadership**

This clause places requirements on 'top management' which is the person or group of people who directs and controls the organization at the highest level. The purpose of these requirements is to demonstrate leadership and commitment by leading from the top. Top management now has greater involvement in the management system and must ensure that the requirements of it are integrated into the organization's processes and that the policy and objectives are compatible with the strategic direction of the organization. In the same context, they need to have a grasp of the organization's internal strengths and weaknesses and how these could impact on the ability to deliver their products or services. This will strengthen the concept of business process management including the need now to allocate specific responsibilities for processes, and demonstrate an understanding of the key risks associated with each process and the approach taken to manage, reduce or transfer the risk. Finally, the clause places requirements on top management to assign QMS relevant responsibilities and authorities. but must remain accountable for the effectiveness of the QMS.

**Clause 6: Planning**

This clause works with Clauses 4.1 and 4.2 to complete the new way of dealing with preventive actions. The first part of this clause concerns risk assessment whilst the second part is concerned with risk treatment. The organization will need to plan actions to address both risks and opportunities, how to integrate and implement the actions into its management system processes and evaluate the effectiveness of these actions.

**Clause 7: Support**

This clause begins with a requirement that organizations shall determine and provide the necessary resources to establish, implement, maintain and continually improve the QMS. Simply expressed, this is a very powerful requirement covering all QMS resource needs. The clause continues with requirements for competence, awareness and communication. Finally, there are the requirements for 'documented information'. This is a new term, which replaces the references in the 2008 standard to 'documents' and 'records'.

**Clause 8: Operation**

This clause deals with the execution of the plans and processes that enable the organization to meet customer requirements and design products and services. It includes much of what was previously referred to in Clause 7 of the 2008 version.

**Clause 9: Performance evaluation**

Performance evaluation covers many of the areas previously featured in Clause 8 of the 2008 version. Requirements for monitoring, measurement, analysis and evaluation are covered and you will need to consider what needs to be measured, methods employed, when data should be analyzed and reported on and at what intervals. Internal audits must also be conducted at planned intervals with management reviews taking place to review the organization's management system and ensure its continuing suitability, adequacy and effectiveness.

**Clause 10: Improvement**

Due to the new way of handling preventive actions, there are no preventive action requirements in this clause. However, there are some new corrective action requirements. The first is to react to nonconformities and take action, as applicable, to control and correct the nonconformity and deal with the consequences. The second is to determine whether similar nonconformities exist, or could potentially occur. The requirement for continual improvement has been extended to cover the suitability and adequacy of the QMS as well as its effectiveness, but it no longer specifies how an organization achieves this.

The change has brought some changes to the terminology used as shown in the table below:

| ISO 9001:2008 | ISO 9001:2015 |
|---|---|
| Products | Products and services |
| Exclusions | Not used |
| Management Representative | Not used |
| Documentation, records | Documented information |
| Work environment | Environment for the operation of processes |
| Purchased product | Externally provided products and services |
| Supplier | External provider |
| Monitoring & Measuring equipment | Monitoring & Measuring resources |

**Documented information**

As part of the alignment with other management system standards a common clause on **'Documented Information'** has been adopted. **The terms "documented procedure" and "record" have both been replaced throughout the requirements text by "documented information".** Where ISO 9001:2008 would have referred to documented procedures (e.g. to define, control or support a process) **this is now expressed as a requirement to maintain documented information**.

Where ISO 9001:2008 would have referred to records this is now expressed as a requirement to retain documented information. Requirements to maintain documented information are detailed throughout the standard and some examples are given. Please read the standard carefully particularly 7.5.

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| **4.3** | Scope of the QMS |
| **4.4** | QMS and its processes |
| **5.2** | QMS policy |
| **6.2** | QMS objectives |
| **7.1.5** | Monitoring and measuring resources |
| **7.2** | Evidence of competence |
| **7.5** | Documented information determined by the organization as being necessary for the effectiveness of the QMS |
| **8.1** | Operational planning and control |
| **8.2** | Determination of requirements for products and services |
| **8.3.5** | Design and development |

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| **8.4** | Control of externally provided products and services |
| **8.5.1** | Production and service provision |
| **8.5.2** | Identification and traceability |
| **8.5.6** | Control of changes |
| **8.7** | Control of non-conforming processes |
| **9.1** | Control of monitoring, measurement, analysis and evaluation |
| **9.2** | Evidence of the audit programme(s) and the audit results |
| **9.3** | Evidence of the results of management reviews |
| **10.1** | Evidence of the nature of the nonconformities and any subsequent actions taken |
| **10.3** | Evidence of continual improvement |

| **Mapping table** | | | |
|---|---|---|---|
| **ISO-9001:2015** | | **ISO-9001:2008** | |
| **4** | Context of the organization | **1.0** | Scope |
| **4.1** | Understanding the organization and its context | **1.1** | General |
| **4.2** | Understanding the needs and expectations of interested parties | **1.1** | General |
| **4.3** | Determining the scope of the quality management system | **1.2**<br>**4.2.2** | Application<br>Quality manual |
| **4.4** | Quality management system and its processes | **4**<br>**4.1** | Quality management system<br>General requirements |
| **5** | Leadership | **5** | Management responsibility |
| **5.1** | Leadership and commitment | **5.1** | Management commitment |
| **5.1.1** | Leadership and commitment for the quality management system | **5.1** | Management commitment |
| **5.1.2** | Customer focus | **5.2** | Customer focus |
| **5.2** | Quality policy | **5.3** | Quality policy |
| **5.3** | Organizational roles, responsibilities and authorities | **5.5.1**<br>**5.5.2** | Responsibility and authority<br>Management representative |
| **6** | Planning for the quality management system | **5.4.2** | Quality management system planning |
| **6.1** | Actions to address risks and opportunities | **5.4.2**<br>**8.5.3** | Quality management system planning<br>Preventive action |
| **6.2** | Quality objectives and planning to achieve them | **5.4.1** | Quality objectives |
| **6.3** | Planning of changes | **5.4.2** | Quality management system planning |
| **7** | Support | **6** | Resource management |
| **7.1** | Resources | **6** | Resource management |

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|---|---|---|---|
| **7.1.1** | General | **6.1** | Provision of resources |
| **7.1.2** | People | **6.1** | Provision of resources |
| **7.1.3** | Infrastructure | **6.3** | Infrastructure |
| **7.1.4** | Environment for the operation of processes | **6.4** | Work environment |
| **7.1.5** | Monitoring and measuring resources | **7.6** | Control of monitoring and measuring equipment |
| **7.1.6** | Organizational knowledge | **New** | |
| **7.2** | Competence | **6.2.1**<br>**6.2.2** | General<br>Competence, training and awareness |
| **7.3** | Awareness | **6.2.2** | Competence, training and awareness |
| **7.4** | Communication | **5.5.3** | Internal communication |
| **7.5** | Documented information | **4.2** | Documentation requirements |
| **7.5.1** | General | **4.2.1** | General |
| **7.5.2** | Creating and updating | **4.2.3**<br>**4.2.4** | Control of documents<br>Control of records |
| **7.5.3** | Control of documented Information | **4.2.3**<br>**4.2.4** | Control of documents<br>Control of records |
| **8** | Operation | **7** | Product realization |
| **8.1** | Operational planning and control | **7.1** | Planning of product realization |
| **8.2** | Determination of requirements for products and services | **7.2** | Customer-related processes |
| **8.2.1** | Customer communication | **7.2.3** | Customer communication |
| **8.2.2** | Determination of requirements related to products and services | **7.2.1** | Determination of requirements related to the product |
| **8.2.3** | Review of requirements related to the products and services | **7.2.2** | Review of requirements related to the product |
| **8.3** | Design and development of products and services | **7.3** | Design and development |
| **8.3.1** | General | **New** | |
| **8.3.2** | Design and development planning | **7.3.1** | Design and development planning |
| **8.3.3** | Design and development Inputs | **7.3.2** | Design and development inputs |
| **8.3.4** | Design and development controls | **7.3.4**<br>**7.3.5**<br>**7.3.6** | Design and development review<br>Design and development verification<br>Design and development validation |
| **8.3.5** | Design and development outputs | **7.3.3** | Design and development outputs |
| **8.3.6** | Design and development changes | **7.3.7** | Control of design and development changes |
| **8.4** | Control of externally provided products and services | **7.4.1** | Purchasing process |
| **8.4.1** | General | **7.4.1** | Purchasing process |
| **8.4.2** | Type and extent of control of external provision | **7.4.1**<br>**7.4.3** | Purchasing process<br>Verification of purchased product |
| **8.4.3** | Information for external providers | **7.4.2** | Purchasing information |
| **8.5** | Production and service provision | **7.5** | Production and service provision |
| **8.5.1** | Control of production and service provision | **7.5.1** | Control of production and service provision |
| **8.5.2** | Identification and traceability | **7.5.3** | Identification and traceability |
| **8.5.3** | Property belonging to customers or external providers | **7.5.4** | Customer property |

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| **8.5.4** | Preservation | **7.5.5** | Preservation of product |
| **8.5.5** | Post-delivery activities | **7.5.1** | Control of production and service provision |
| **8.5.6** | Control of changes | **7.3.7** | Control of design and development changes |
| **8.6** | Release of products and services | **8.2.4**<br><br>**7.4.3** | Monitoring and measurement of processes<br>Verification of purchased product |
| **8.7** | Control of nonconforming process outputs, products and services | **8.3** | Control of nonconforming product |
| **9** | Performance evaluation | **New** | |
| **9.1** | Monitoring, measurement, analysis and evaluation | **8** | Measurement, analysis and improvement |
| **9.1.1** | General | **8.1** | General |
| **9.1.2** | Customer satisfaction | **8.2.1** | Customer satisfaction |
| **9.1.3** | Analysis and evaluation | **8.4** | Analysis of data |
| **9.2** | Internal audit | **8.2.2** | Internal audit |
| **9.3** | Management review | **5.6** | Management review |
| **10** | Improvement | **8.5** | Improvement |
| **10.2** | Nonconformity and corrective action | **8.3**<br>**8.5.2** | Control of nonconforming product<br>Corrective action |
| **10.3** | Continual Improvement | **8.5.1** | Continual Improvement |

**TRANSITION GUIDANCE**

**1. Existing CCPL Clients of ISO 9001:2008:**

**ISO 9001: 2015 Transition**

Organizations already certified to ISO 9001:2008 have three years from publication of the new version in which to transfer. This transition period ends in September 2018. No certificate of QMS shall bear the expiry date later than 15th Sept' 2018 as all the ISO 9001:2008 certificates will be invalid after this particular date i.e. 15th Sept' 2018.

Please note that if your organization does not have a transition audit prior to the end of the transition period/obsolescence date of ISO 9001:2008, and then you will no longer be certified as of the end of the transition period. In order to become certified to ISO 9001:2015, you will need to start over with an initial audit (Stage 1 and Stage 2).

However in this journey of transition, CCPL operational department will work with you to ensure the timely scheduling of any transition audits that occur later in the transition period to avoid any unfortunate situation.

Based on the agreement with you, CCPL is in a potential to conduct transition activities during a routine surveillance, recertification audit or on request a special audit.

Please note that the new standard was published on September 15, 2015. This means that the ISO 9001:2008 standard will become obsolete on September 15, 2018. As a result, All ISO 9001:2008 certifications issued from 15$^{th}$ September 2015 and beyond will have to bear an expiry date of September 15, 2018.

CCPL will accept a client undergoing surveillance with ISO 9001:2008 version only till 15th September 2017. We are sending out this communiqué in advance so that you may prepare well.

However if a client on special request puts up a request not to be able to entertain ISO 9001:2008 version in 31st March 2017, we may consider the client in up to 15th September 2017.

**Please note that 1st July 2016 onwards CCPL shall be ready to take up any client which requests its certification/surveillance against ISO 9001:2015.**

**Certification assessment as per ISO 9001:2015 will be conducted in two stages (Stage-1 and stage-2). Stage-1 audit (Document conformity assessment) and stage-2 audit (Compliance assessment) will be conducted onsite.**
**Surveillance /transition audit will be conducted in two stages (Stage-1 and stage-2). Please note that the Stage-1 of the transition audit will be offsite and stage-2 will be onsite at client premises. Recertification under ISO-9001:2008 is valid till 15th September 2016. Thereafter first surveillance audit will be conducted as transition audit to ISO 9001:2015 on or before 15th September 2017.**

**2. New client**

If an organization is not yet certified & has been working at implementing ISO 9001:2008 for a while, CCPL appreciates that a lot of work may have gone into preparing for certification to ISO 9001:2008. CCPL will allow initial audits to the 2008 version of the standard however keeping in mind that ISO 9001:2008 will be obsolete on September 15, 2018.

The expiration date on any ISO 9001:2008 certificates issued after the publication of ISO 9001:2015 will be September 15, 2018. Thus, it may appear that you are not being granted a full, three-year certificate. However, after successful transition to ISO 9001:2015, the expiry date of your certificate will be amended to reflect a full three-year certification. In any of the cases, it is important to avoid waiting until the last minute.

Please support CCPL to ensure the following during Transition activities:

1. All issues that require your action for compliance with the new requirements be clearly identified and raised as documented findings.
2. Only when all identified outstanding issues have been appropriately addressed and the effectiveness of the management system demonstrated, the auditors recommend certification to the published ISO 9001:2015 standard for your organization.
3. Your QMS records are verified to demonstrate that all prior transition audit findings have been evaluated for corrective action and compliance before any recommendation for approval to ISO 9001:2015 be made.
4. CCPL ensures that the evaluation of your conformance to the new requirements during the transition phase does not interfere with your ongoing conformance to ISO 9001:2008.