

**ISO 9001:2015 CLIENT GAP ANALYSIS TOOL**

**Instructions For Use**

This gap analysis document provides a simple framework for evaluating your quality management system against the requirements of ISO 9001:2015. It is split into two tables:

* **Part 1: New concepts** – highlighting the new concepts introduced in ISO 9001:2015 and the related clauses, processes and functional activities
* **Part 2: Requirements** – highlighting new and amended clauses between ISO 9001:2008 and ISO 9001:2015

Please complete each table by recording the evidence acquired from one full internal audit against the requirements of ISO 9001:2015.

If you are unable to provide evidence of compliance, you may not be ready to complete the transition to ISO 9001:2015. In this case, please inform KAYZED that you need additional time to prepare for the transition – we will work with you to select a mutually agreeable date to complete the transition.

**Please ensure that this completed document and internal audit records are available to your auditor at the opening meeting of your transition audit**.

Sections marked as ***(Assessor to Complete)*** will be completed by the assessor during the transition audit.

Client name:

Certificate number:

Date of completion:

**Part 1: New Concepts**

Tip: Ensure that these new concepts have been deployed in a manner that supports the *Process Approach* and *Risk Based Thinking*.

| **New Concepts** | **Phase** | **Clause(s)** | **Activity** | ***(Client to Complete)******Evidence of compliance*** | ***(Assessor to Complete)******Has the Client Demonstrated they have Met the requirements of this clause?*** | ***(Assessor to Complete)******Comments if Required*** |
| --- | --- | --- | --- | --- | --- | --- |
|  |  | ***Yes***  | ***No*** |  |
| Business Planning and Strategic Direction  | Identify | 4.1, 4.2 | Have youidentified both internal and external issues and interested parties that are relevant to and/or support the strategic direction of your organisation? |  |  |  |  |
|  | Assess | 4.1, 4.2, 5.1.1, 9.3.2,  | Is the strategic direction being assessed, reviewed and aligned with the quality policy and objectives by top management? |  |  |  |  |
| New requirement for the adoption of a process approach(where before this was suggested) | Identify | 4.4 | Has planning for the quality management system determined the processes of your organisation, their inputs and outputs and sequence and interaction? Is monitoring and measurement of the processes in place? Are processes documented to the extent necessary to support their operation? Is documented information available to provide confidence that the processes are being carried out as planned? |  |  |  |  |
|  | Action | 5.2.1 | Is the strategic direction being utilised as an input to the Quality Policy / Quality Objectives / Risk Management / Management Review processes? |  |  |  |  |
| Process Risk | Identify | 6.1, 6.2 | Have risks to achieving process objectives been identified – ie what problems or mistakes might occur? |  |  |  |  |
|  | Assess | 4.4.1,6.3 | Have these risks been considered and addressed when establishing the QMS and when planning for change to the QMS – ie what checks and balances have you incorporated into your activities to prevent problems or mistakes? |  |  |  |  |
|  | Action | 6.3, 8.5.6 | Are process risks, (ie potential problems or errors), considered during planning for change, and following unintended change, to ensure requirements continue to be met. |  |  |  |  |
|  | Action | 10.2.1 | Following corrective action, is there evidence that process risks have been reviewed, ie checks made to ensure the problem does not occur again, or new problems, (risks) are not introduced. |  |  |  |  |
|  | Monitor | 9.1.3,9.3.2 | Are you analysing the effectiveness of actions taken to address process risks? How do you know your processes are effective and efficient? |  |  |  |  |
| Product Risk | Identify | 5.1.2, 6.1, 6.2, 8.3.2 | Have you identified the barriers or risks to achieving product or service compliance? Has product complexity been considered during design planning? |  |  |  |  |
|  | Assess | 8.1 | Have these barriers/risks been considered as part of your planning of operations? |  |  |  |  |
|  | Assess | 8.2.2, 8.2.3 | Have these product risks been considered when determining and reviewing your customer requirements? |  |  |  |  |
|  | Action | 8.3.4, 8.1 | Are the selected design and operational controls sensitive to the identified risks – ie appropriate for the likely consequences of failure? |  |  |  |  |
|  | Monitor | 9.1.3,9.3.2 | Are you analysing the effectiveness of the above actions, (taken to address product risks)? |  |  |  |  |
| Risk to the provision of externally provided product (outsourcing) | Identify | 6.1 | Have risks associated with externally provided product and services, (outsourcing), been identified? For example, have you applied some form of criticality measure or rating, (formal or informal), to your subcontractors? |  |  |  |  |
|  | Assess | 8.4.1, 8.4.2 | Do identified risks or criticality determine or influence the type and extent of controls or oversight applied to the * selection of external resources or suppliers
* controls or oversight applied to these external resources or suppliers
* degree of information provided to these external resources or suppliers?
 |  |  |  |  |
|  | Monitor | 9.1.3,9.3.2 | Are you analysing the effectiveness of actions taken to address risks arising from the use of external resources - subcontractors or suppliers? |  |  |  |  |

**Part 2: ISO 9001:2015 Requirements**

Tip: ensure that you can demonstrate that each requirement of ISO 9001:2015 has been addressed within the QMS.

| **ISO 9001:2015** | **ISO 9001:2008 Cross Reference and the significant changes from the 2008 version** | ***(Client to Complete)******Evidence of compliance*** | ***(Assessor to Complete)******Has the Client Demonstrated they have Met the requirements of this clause?*** | ***(Assessor to Complete)******Comments if Required*** |
| --- | --- | --- | --- | --- |
|  |  |  |  |
| 4.1 Understanding the organisation and its context  | New Requirement: addressed in part 1 above |  |  |  |  |
| 4.2 Understanding the needs and expectations of interested parties | New Requirement: addressed in part 1 above |  |  |  |  |
| 4.3 Determining the scope of the quality management system  | 4.2.2 - Have exclusions including justifications been included in the scope.Have external and internal issues and interested parties been considered? |  |  |  |  |
| 4.4 Quality management system and its processes  | 4.1 – Has the assignment of responsibilities been completed and have the risks and opportunities been determined |  |  |  |  |
| 5.1 Leadership and commitment  | 5.1 – Can top management demonstrate their degree of leadership and commitment to the QMS |  |  |  |  |
| 5.2 Quality policy  | 5.3 – Is the policy appropriate to the purpose and context of the organisation and does it support the strategic direction of the company? |  |  |  |  |
| 5.3 Organisational roles, responsibilities and authorities  | 5.5.2 – Have the responsibilities for maintaining the QMS been determined |  |  |  |  |
| 6.1 Actions to address risks and opportunities | New Requirement |  |  |  |  |
| 6.2 Quality objectives and planning to achieve them  | 5.4.1 – Do the objectives support the policy which supports the strategic direction of the organisation |  |  |  |  |
| 6.3 Planning of changes  | 5.4.2 – When changes occur do you consider the potential consequences of those changes? |  |  |  |  |
| 7.1.1 – 7.1.2 Resources (People) | 6.1 – Have resource needs been determined |  |  |  |  |
| 7.1.3 – 7.1.4 Resources (Infrastructure and Environment) | 6.3, 6.4 – Has the environment been determined and is being maintained |  |  |  |  |
| 7.1.5 Monitoring and measuring resources | 7.6 – When measuring equipment is found to be unfit for purpose is appropriate action as necessary taken and is this consistently applied. |  |  |  |  |
| 7.1.6 Organisational knowledge | New Requirement |  |  |  |  |
| 7.2 Competence  | 6.2.1, 6.2.2 – Largely unchanged |  |  |  |  |
| 7.3 Awareness  | 6.2.2 – Do induction training plans and training records demonstrate how the organisation is communicating the implications of not conforming with the quality management system requirements |  |  |  |  |
| 7.4 Communication  | 5.5.3 – Has a communication strategy been determined and communicated. |  |  |  |  |
| 7.5 Documented information  | 4.2.1, 4.2.3 – Existing procedures for document and record control may meet many of these requirements. Have these been reviewed accordingly? |  |  |  |  |
| 8.1 Operational planning and control  | 7.1 – Is there consideration given to risk identification, (ie potential errors and non conformities), and change control during operational planning |  |  |  |  |
| 8.2 Determination of requirements for products and services  | 7.2 – Does the organisation have a process in place to ensure that it can meet the claims for the products and services it offers. |  |  |  |  |
| 8.3 Design and development of products and services  | 7.3 – Does the design process consider risk and complexity of product and tailor itself accordingly, is there evidence of a connection between the risk identification process and involvement of external resources, (ie outsourcing or sub contractors). |  |  |  |  |
| 8.4 Control of externally provided products and services  | 7.4 – Have you considered outsourced processes? Is there evidence of a connection between the risk identification process and the level of control being applied. See part 1 earlier. |  |  |  |  |
| 8.5 Control of production and service provision | 7.5 – Does the extent of post-delivery activities take into consideration the potential undesired consequences associated with its products and services |  |  |  |  |
| 8.5.6 Control of changes \* | n/a |  |  |  |  |
| 8.6 Release of products and services  | 8.2.4 – Are planned arrangements for product release driven from risk identification, ie based upon likely failures and the steps needed to prevent these failures? |  |  |  |  |
| 8.7 Control of nonconforming process outputs, products and services  | 8.3 – Segregation and containment are now options for addressing nonconforming outputs, procedures may need to be updated.  |  |  |  |  |
| 9.1 Monitoring, measurement, analysis and evaluation  | 8.1, 8.2.1, 8.4 – Is there a flow down from risk identification to what needs to be measured and monitored and then evidence that this data is not just being collected but also evaluated.  |  |  |  |  |
| 9.2 Internal audit  | 8.2.2, 8.2.3 – Audit results can now be reported to relevant management not just the management responsible for the area being audited, this may require a documented information update |  |  |  |  |
| 9.3 Management review  | 5.6.1, 5.6.2 – Note the inclusion of a review of any changes to internal and external issues as well as the effectiveness of actions taken to address identified risk and opportunities.  |  |  |  |  |
| 10.1 General – Improvement  | 8.5.1 – Have you determined and selected opportunities for improvement  |  |  |  |  |
| 10.2 Nonconformity and corrective action  | 8.5.2 – Do you have a closed loop process from the corrective action process back to risk identification and review. |  |  |  |  |
| 10.3 Continual improvement  | 8.5.1 – Is a process for continual improvement being utilised. How is improvement encouraged and acknowledged? |  |  |  |  |

**Areas for further investigation:**

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