Gap Analysis Checklist

ISO 9001:2015 Self-assessment

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Gap Analysis Checklist – Part A

Clause 4 - Context of the Organization

4.1 Understanding the Organization and its Context

Your organization is now required to identify and asses all internal and external issues that could impact upon your quality management system's ability to deliver its intended results. You will need to develop a methodology to understand the needs and expectations of all interested parties. Collate evidence to provide assurance that your organization is regularly, or as necessary, reviewing and updating its external and internal issues.

Ref	Gap Analysis Question	Gap Finding			Action Plan (if OFI or NC)		Notes
		Comply	**OFI [1]**	**NC [2]**	Improvements Needed [OFI 1]	Corrective Action Needed [NC 2]	Objective Evidence & Comments
1	Has your organization determined the external and internal issues (values, culture, knowledge and performance) that affect the ability to achieve intended results?						
2	Has your organization considered international, national, regional or local issues arising from legal, technological, competitive, market, cultural, social and economic environments?						
3	Are these issues reviewed and monitored on a regular basis, how often does your organization review these issues?						

4.2 Understanding the Needs and Expectations of Interested Parties

The intent of this requirement is to ensure that your organization considers the requirements of relevant interested parties beyond those of your customer. The intention is to focus on the interested parties which are relevant to the quality management system (QMS).

Ref	Gap Analysis Question	Gap Finding			Action Plan (if OFI or NC)		Notes
		Comply	**OFI [1]**	**NC [2]**	Improvements Needed [OFI 1]	Corrective Action Needed [NC 2]	Objective Evidence & Comments
3	Have the needs and expectations of interested parties that are relevant to the QMS been determined?						
4	Has your organization determined all the interested parties' requirements?						
5	Does your organization monitor and review information about these interested parties and their relevant requirements? If so, what process is used and how frequently is it performed?						

4.3 Determining the Scope of the Quality Management System

Look for confirmation that your organization has determined the boundaries and applicability of the QMS to establish its scope with reference to any external and internal issues referred to in 4.1 and the requirements of relevant interested parties referred to in 4.2. All requirements within the standard are to be met unless they do not apply. The scope of your QMS may include the whole of the organization, specific and identified functions within the organization, specific sections of the organization, or one or more functions across a group of organizations.

Ref	Gap Analysis Question	Gap Finding			Action Plan (if OFI or NC)		Notes
		Comply	**OFI [1]**	**NC [2]**	Improvements Needed [OFI 1]	Corrective Action Needed [NC 2]	Objective Evidence & Comments
6	Has your organization determined the boundaries and applicability of your quality management system to establish its scope?						