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We're committed to helping you and your organization understand and implement the requirements of ISO 9001:2015. This guidance document identifies the steps for undertaking a gap analysis of your quality management system.

# Gap Analysis Guidance

**ISO 9001:2015 Self-assessment**

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# Gap Analysis Guidance

## Introduction

### What is a Gap Analysis?

A gap analysis is a type of survey instrument that is used to determine the differences (gaps, also known as a 'delta') between an organization's management system and the requirements of controlling criteria, such as standards like ISO 9001:2015.

A gap exists where existing policies, processes or procedures do not fully meet the stated requirements.

This gap analysis checklist highlights and summarises the requirements contained in ISO 9001:2015, it is not intended to cover all of the requirements from the standard comprehensively, only an overview of them.

It is used to capture the gaps in your organization's management system and the requirements of ISO 9001:2015, with the goal of determining:

1. What existing company processes and procedures already meet ISO 9001 requirements;
2. What existing procedures and processes need to be modified to meet ISO 9001 requirements;
3. What additional procedures and processes need to be created to meet ISO 9001 requirements.

Make sure that you purchase copies of ISO 9000:2015 and ISO 9001:2015. Read them both and make yourself familiar with their language and concepts. Although it is written in a dense, formal language, the clause titles in ISO 9001:2015 are fairly self-explanatory.

### What Does a Gap Analysis Involve?

While the process to becoming ISO 9001 certified is complex, the process of running a gap analysis is considerably less complicated. There are five major steps in the process for completing a gap analysis of ISO 9001, you can read more about these steps in the next section of this document.

Your organization may already have in place a compliant quality management system or you might be running an uncertified system; the gap analysis checklist provides a structured framework to help assess the current status of your QMS in terms of fulfilling the requirements ISO 9001:2015.

After the gap analysis, you should have a clear picture of how your existing quality management system compares with the requirements of ISO 9001. In general, the steps for conducting a gap analysis are:

1. Reviewing what is the present operation/process and what already exists;
2. Analyzing the relevant sections of the ISO 9001 standard to determine what is actually required;
3. Documenting the differences or gaps.

These differences and gaps should be organized into a detailed findings list, for review and approval by top management.

In summary, the gap analysis should include a review of all processes and procedures for management controls and technical controls, such as for sampling, method validation, equipment calibration, qualification and maintenance, employee qualifications, and others.

The unique knowledge obtained about the status your existing quality management system will be a key driver of the subsequent implementation approach.

## What Does a Gap Analysis Achieve?

Using the output of the gap analysis, you can develop a findings list, which can include additional tasks such as selecting and dealing with an accreditation or certification body.

Not only will this gap analysis template help you to identify the gaps, it will also allow you to recommend how those gaps should be filled.

Armed with this knowledge, it allows you to establish accurate budgets, timelines and expectations which are proportional to the state of your current management system when directly compared to the requirements of the standards.

The gap analysis output, in the form of a findings list provides a valuable baseline for the implementation process as a whole, and for measuring progress.

Try to understand each business process in the context of each of the requirements by comparing different activities and processes with what the standard requires.

At the end of this activity you will have a list of activities and processes that comply and ones that do not comply. The latter now becomes the findings list and the target of your action plan.

## Using the Gap Analysis Checklist

This gap analysis checklist is aligned with the requirements of ISO 9001:2015, and it is imperative that gap analysis is undertaken with due reference to the standard. The gap analysis tool is divided into seven sections, which reflect the contents of ISO 9001:2015. The two gap analysis tools, Part A and Part B, listed below provide a structured framework to assess the current status of a QMS in terms of fulfilling the ISO 9001 clauses:

**Part A** comprises the gap analysis checklist which is aligned with the clauses of ISO 9001 and provides comments and notes to assist users.

**Part B** comprises the gap analysis findings list which details the gaps and proposed remedial actions that are required to close the identified gaps between ISO 9001 and your current management system.

Each question in the gap analysis checklist should be assessed by auditor for conformance to the requirements of ISO 9001, along with the auditor's knowledge of your organization's products, services, processes, and facilities; they will be able to make a judgement on conformity, using the criteria set out in the table below:

| Gap Finding | Meaning | Description |
|---|---|---|
| **Comply** | Complies with stated requirements | The organization has objective evidence to support the question, and/or |
| | | The organization has a documented procedure or process |
| **OFI** | Improvement actions are needed to comply | The organization has objective evidence, but procedure or process needs improvement, and/or |
| | | The organization has objective evidence, but no documented procedure or process, and/or |
| | | The organization has a documented procedure, but is lacking some objective evidence to support the question |

| Gap Finding | Meaning | Description |
|---|---|---|
| **NC** | Nonconformance | The organization has no objective evidence to support the question, and/or |
| | | The organization is lacking a documented procedure or process, and/or |
| | | The organization is lacking objective evidence to support compliance |