# Gap Analysis Guidance

ISO 9001:2015

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# 1 Introduction

Building an QMS (Quality Management System) that meets the requirements of ISO 9001:2015 can be challenging. If you are in doubt about the interpretation of any particular requirements and your business's current status against it, you should refer to BS EN ISO 9004:2018, the guidance standard.

The gap analysis of your management system will provide a high-level overview of your current system against the standard's requirements. It is an ideal solution for organizations that must measure their current state of compliance against the standard and identify the actions required to address any gaps.

The gap analysis checklist is not intended to be a comprehensive verification of all the ISO 9001:2015 standard requirements; however, it will assist you in understanding the effectiveness of your current management system and identify gaps in processes not previously considered.

## 1.1 Businesses With an Existing QMS

For businesses with an existing quality management system, you may decide to keep your current quality management system and simply amend and adapt it where necessary. Some of you may take this as an opportunity for a complete revamp of the management system. If you have an existing ISO 9001 quality management system, then you should:

1. Determine your resourcing requirements to include additional training. (e.g., attending a Managing ISO 9001:2015 or an Internal Auditing course?);
2. Undertake a thorough gap analysis of the existing quality management system and supporting business processes using our ISO 9001:2015 Gap Analysis Checklist.docx. Consider all questions in sections 4 to 10 and provide references to your system documented information (as appropriate) in the corresponding column;
3. Develop the ISO 9001:2015 Gap Analysis Action Plan.xlsx. This is the output of the gap analysis and should outline the timeline of actions required to close the gaps;
4. Once the quality management system has been updated, 'run' the system for at least four months to embed it into the organization, identify and address nonconformities, and implement any improvement opportunities;
5. Engage with your Certifying body to arrange certification!

Iterative adjustment of new or existing management system documentation should also be expected as staff become accustomed to the requirements and begin to suggest usability improvements. Instant business or operational improvements may initially be observed.

If you have a compliant quality management system, begin with the assumption that you already do most of what ISO 9001:2015 requires. You probably are! Here are some initial review tasks to consider:

1. Identify legal and regulatory compliance requirements related to quality management system performance;
2. Compare actual performance with external standards, regulations, codes of practice and guidelines;
3. Identify activities, products, and services that can create quality risks and/or pose legal risks;
4. Review existing management procedures;
5. Compare actual operations with internal policies and procedures;
6. Identify policies and procedures dealing with external contracts for services and suppliers;
7. Review investigations of previous incidents, accidents, and 'near misses';

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also should determine the size of the gaps. These findings will lead to recommendations, project plans, and the identification of necessary resources for filling the gaps.

## 1.4 Using the Gap Analysis Tools

These gap analysis tools are aligned with the requirements of ISO 9001:2015, and gap analysis must be undertaken with due reference to the standard to develop a workable implementation plan.

The three gap analysis tools, Part A, Part B, and Part C, listed below provide a structured framework to assess the current status of your management system in terms of fulfilling the ISO 9001 clauses:

### 1.4.1 Part A - Gap Analysis Checklist

**Part A** comprises the gap analysis checklist, which is aligned with the clauses of ISO 9001 and provides comments and notes to assist users. Use the gap analysis checklist to compare the standard's requirements against your organization's existing management system. Each question in the checklist refers to a requirement that must be met to comply with ISO 9001:2015.

The gap analysis checklist is divided into seven sections, which reflect the contents of ISO 9001:2015. The requirements of ISO 9001:2015 are paraphrased, and the user must take care to review the ISO 9001:2015 standard to understand all specific requirements.

The 'Comply' box should be ticked when the objective evidence demonstrates conformity. The 'NC' box should be ticked if the objective evidence demonstrates a nonconformity. An 'Opportunity for Improvement' (OFI) may exist in the same question, but an OFI may not be issued for an issue that does not conform.

Each question in the gap analysis checklist should be assessed by the 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 judgment on conformity, using the criteria set out in the table below:

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

### 1.4.2 Part B - Findings List

**Part B** comprises the gap analysis findings list, which details the gaps and the proposals for remedial action that are required to close the identified gaps between ISO 9001 and your current management system. It clearly

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