ISO 9001:2026 Gap Analysis Checklist

HSQ Edition — ISO 9001:2026/45001:2018

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Gap Analysis Guidance

Introduction

A gap analysis is a tool for seeing how your quality management system measures up to the requirements of ISO 9001. Its purpose is to help your business determine the gaps with respect to these requirements. A gap analysis should be conducted as an initial step when implementing the requirements of ISO 9001:2026.

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 9001:2026. A gap exists where existing policies, processes, or procedures do not fully meet the stated requirements.

This gap analysis checklist highlights and summarizes the requirements contained in ISO 9001:2026; it is not intended to cover all of the requirements from the standard comprehensively, only an overview of them, and is used to capture the gaps in your organization's management system and the requirements of ISO 9001:2026, with the goal of determining:

- What existing company processes and procedures already meet ISO 9001 requirements?
- What existing procedures and processes need to be modified to meet ISO 9001 requirements?
- What additional procedures and processes need to be created to meet ISO 9001 requirements?

Make sure that you purchase copies of ISO 9000:2026 and ISO 9001:2026. Read them both and make yourself familiar with their language and concepts. Although it is written in dense, formal language, the clause titles in ISO 9001:2026 are fairly self-explanatory.

What Does a Gap Analysis Involve?

While the process of 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 of 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 HSQ management system in terms of fulfilling the requirements of ISO 9001:2026.

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:

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

These differences and gaps should be organized into a detailed task 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 sampling, method validation, equipment calibration, qualification and maintenance, employee qualifications, and others.

The unique knowledge obtained about the status of 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, but it will also allow you to recommend how those gaps should be filled. Armed with this knowledge, you can establish accurate budgets, timelines, and

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expectations that 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 task list and the target of your implementation plan.

Using the Gap Analysis Checklist

This gap analysis checklist is aligned with the requirements of ISO 9001:2026, and gap analysis must be undertaken with due reference to the standard. The gap analysis tool is divided into seven sections, which reflect the contents of ISO 9001:2026. The two gap analysis tools, Part A and Part B, listed below provide a structured framework to assess the current status of an HSQ management system 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, while 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 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:

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	Opportunity for Improvement — improvement actions are needed to comply	The organization has objective evidence, but the procedure or process needs improvement; or the organization has objective evidence but no documented procedure or process; or the organization has a documented procedure but is lacking some objective evidence to support the question
NC	Nonconformance — action required	The organization has no objective evidence to support the question; or the organization is lacking a documented procedure or process; or the organization is lacking objective evidence to support compliance

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Gap Analysis Checklist — Part A

Complete the gap analysis checklist below and one full internal audit against the ISO 9001:2026 requirements prior to your organization's certification audit. Please complete the tables below, which highlight some of the concepts and themes present in ISO 9001:2026. These concepts will bridge multiple processes, clauses, and functional areas. Ensure that the completed checklist and internal audit records are available prior to commencing formal assessment.

Questions flagged as new in 2026 are highlighted with a light-green background in the question column, and the commentary for each affected sub-clause summarizes what has changed. If you are transitioning from ISO 9001:2015, focus first on the flagged questions. If you are taking your first steps in implementing the 2026 edition, answer all of the questions.

Clause 4 — Context of the Organization

4.1 Understanding the Organization and its Context

Your organization is required to identify and assess all internal and external issues that could impact 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. New in ISO 9001:2026: the organization must determine whether climate change is a relevant issue (carried into the standard from Amendment 1:2024).

Ref	Gap Analysis Question	Gap Finding			Action Plan (if OFI or NC)		Objective Evidence & Comments
		Comply	OFI [1]	NC [2]	Improvements Needed [OFI 1]	Corrective Action Needed [NC 2]	
1	Has your organization determined the external and internal issues (values, culture, knowledge, and performance) that affect the ability to achieve intended results?						
2	**NEW FOR 2026** Has your organization considered international, national, regional, or local issues arising from the effects of climate change, 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 that are relevant to the HSQ management system. New in ISO 9001:2026: a note recognizes that relevant interested parties can have requirements related to climate change.

Ref	Gap Analysis Question	Gap Finding			Action Plan (if OFI or NC)		Objective Evidence & Comments
		Comply	OFI [1]	NC [2]	Improvements Needed [OFI 1]	Corrective Action Needed [NC 2]	
4	Have the needs and expectations of interested parties that are relevant to the HSQ management system been determined?						

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5	**NEW FOR 2026** Has your organization determined all the interested parties' requirements, including those related to climate, and which of these requirements will be addressed through the HSQ management system?						
6	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 Integrated Management System

Look for confirmation that your organization has determined the boundaries and applicability of the HSQ management system 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 HSQ management system 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)		Objective Evidence & Comments
		Compl y	OFI [1]	NC [2]	Improvements Needed [OFI 1]	Corrective Action Needed [NC 2]	
7	Has your organization determined the boundaries and applicability of your quality management system to establish its scope?						
8	When determining the scope, did your organization consider: a) the external/internal issues 4.1? b) the requirements of interested parties 4.2? c) Its products and services?						
9	Has your organization applied all the requirements of ISO 9001:2026 if they are applicable to the scope of your HSQ management system?						
10	Is the scope of your organization's quality management system available as documented information?						
11	Does the scope state the types of products and services covered, and justify any requirement from ISO 9001:2026 – Clause 8 that our organization has determined is not applicable to the scope of the HSQ management system?						
12	Is the organization aware that conformity to ISO 9001:2026 may only be claimed if the requirements that are determined 'as not applicable' do not affect your organization's ability or responsibility to ensure the conformity of products and services, and the enhancement of customer satisfaction?						

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Gap Analysis Findings List — Part B

Implementation Plan

Where gaps have been identified, these should be included in the findings list. This plan should detail the gaps and the actions to be taken (what, when, and by whom) to correct and implement the outstanding HSQ management system components. The plan should define responsibilities of different departments and personnel and set target dates for the completion of tasks. Once approved, the HSQ Manager should control, review, and update the plan as documentation and the implementation process proceeds.

Clause 4 — Context of the Organization

Clause Ref	Description of Gap Identified	Proposed Remedial Action	OFI [1]	NC [2]	Process Owner	Date Completed

Clause 5 — Leadership

Clause Ref	Description of Gap Identified	Proposed Remedial Action	OFI [1]	NC [2]	Process Owner	Date Completed

Clause 6 — Planning

Clause Ref	Description of Gap Identified	Proposed Remedial Action	OFI [1]	NC [2]	Process Owner	Date Completed

Clause 7 — Support

Clause Ref	Description of Gap Identified	Proposed Remedial Action	OFI [1]	NC [2]	Process Owner	Date Completed

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