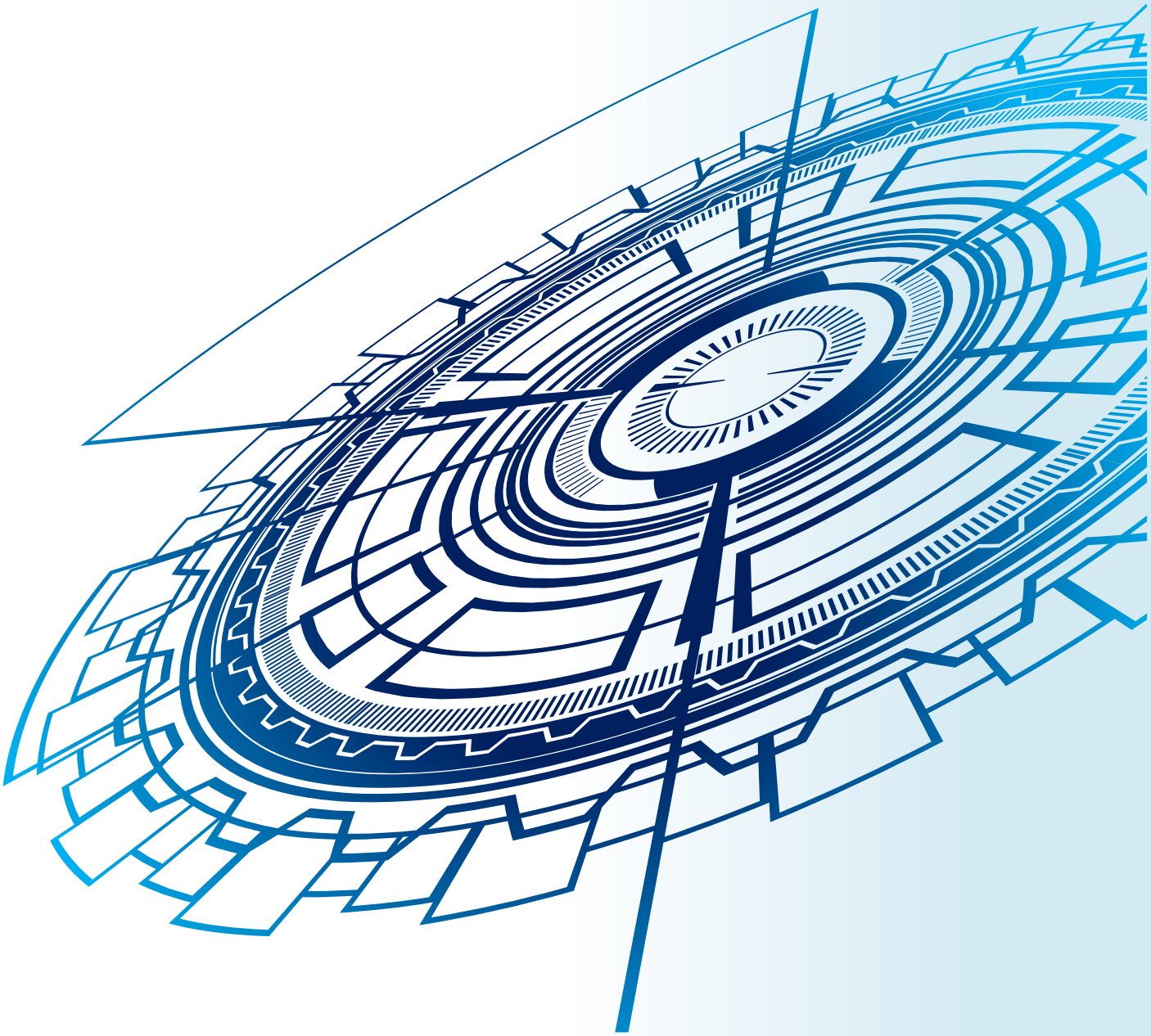
ISO 9001:2015

IMPLEMENTATION GUIDE



WHY IS ISO IMPORTANT?

The International Organisation for Standardisation (ISO) is a multi-national organisation that puts forth internationally recognised standards that provide structured frameworks of doing business efficiently and effectively. ISO is an independent, non-governmental organisation, consisting of 164 member countries. ISO was initiated with the idea of answering a fundamental question: "What is the best way to do business?"

The ISO certification mark confirms that your business complies with certified international practices to ensure that your organisation is a reliable and trustworthy service provider, attracting prospective clients and stakeholders.

Customers, regulators, and governments rely on ISO standards to help develop better regulations for businesses in their country. By trusting globally recognised experts to deliver globally agreed upon standards and template frameworks, you can be assured that ISO standards are worth complying to.

ISO Certifications are a means to qualify businesses. This ensures that a certified organisation has a robust Business Management System comprising of Policies, Objectives, Plans, Processes, Procedures, Risk Assessments, Consistent Forms, Templates, and Standardisation. The purpose of standardisation is to streamline production in various industries, ensuring the quality, consistency, and safety of products and services, while supporting global collaboration and compatibility.

There are many benefits of standardisation for businesses. Customer satisfaction is a key element to success for any business. By complying with various ISO standards, you will ensure that your products and services are delivered at optimal levels of quality. ISO certification is seen as a stamp of approval. By implementing these standards, it increases and streamline productivity, cut costs, and reduce errors.

ISO implementation will aid both short- and long-term business strategies to help a business run smoothly, no matter the size or industry of the business. ISO Management Systems gives every business a competitive advantage over a competitor that does not comply with or implement such a framework in their business. By implementing a Management System that complies with international standards, you will ensure customer satisfaction through quality products and services.

INTRODUCTION

International Standards are long used as a business improvement tool to help drive continual improvement and deliver results in your organization. It is well known that implementation of a Management System transcends well past a piece of paper, and enters the real world as not only being a "stamp of approval" but also an operational tool which results in competitive advantage and an instrument which leverages growth.

Working in hand with the culture of your organisation, Management Systems present a fool-proof strategy to ensure that customer satisfaction, quality, and performance form a solid foundation to your organisation. As technological advantages disrupt industries and leave many poorly-prepared companies in their wake, the framework provided by these international Standards help predict volatility, and allow you to get ahead of the curve by predicting changing requirements, ensuring your satisfaction levels shift with the tides of change. International Standards are rigid enough to ensure consistent and comparable results, but flexible enough to bend and sway with the requirements of your organisation.

This Implementation Guide will assist you through the process of establishing a Quality Management System in accordance with the requirements of ISO 9001:2015.

NOTE: Specific reference should be made to the ISO 9001:2015 STANDARD: UNVEILED section of this document.

This guide is laid out to cover the specific requirements of each clause of the Standard, to give additional detail and provide direction. Specific tips have been included, in addition to clause descriptions, to ensure that your establishment and implementation process runs as smoothly as possible. It is also important to note that many Management Systems are closely related and may share the same requirements. Although the clause structure may appear identical, there are multiple technical, legal, and other requirements that must be met to be certified.

Furthermore, as this guide does not contain the text of the ISO 9001:2015 Standard, users are recommended to obtain a copy from their national standards body or from ISO, either directly via sales@iso.org or via the Internet from www.iso.org.

> Quality is never an accident; it is always the result of high intention, sincere effort, intelligent direction, and skilful execution; it represents the wise choice of many alternatives.
>
> - *William A. Foster*

COMMITMENT

FEEDBACK

MOTIVATION

REVIEW

KNOWLEDGE

ISO 9001:2015 STANDARD: UNVEILED

Implementation Guide

These state-of the-art templates enable your company to utilize robust and effective processes to improve the overall quality of all your company's processes. Based on the seven Quality Management Principles as well as a Plan-Do-Check-Act Model, these templates utilize multiple avenues to ensure focused results. The multiple benefits of utilizing templates for ISO 9001:2015 include significantly improved control over aspects of your business, ensuring consistent and comparable results, negative impact factor identification, as well as risk and opportunity prioritization. With concentration on meeting the requirements and expectations of customers, interested parties, and stakeholders – as well as enhancing their satisfaction – business metrics and data are analysed to best identify strengths, weaknesses, opportunities, and threats. Alleviating your administrative burden and frustration regarding often difficult to interpret clauses and expectations – these templates offer a unique competitive advantage by being adaptable to your company's size and industry. These templates allow you to take full advantage of the framework to provide consistent and reliable results as well as ensure continual improvement and innovation.

Purpose of Toolkit

Building a Management System from the ground is a daunting and daring task – yet it is the cornerstone of every successful certification process. We have assisted various organizations to achieve certification to a range of Standards – showcasing our expert ability to provide direction and support. Our WWISE ISO Experts have spent many years perfecting, streamlining, and updating our templates to ensure your company can implement ISO 9001:2015 in-house, with practiced guidance and support.

These templates are formulated to integrate seamlessly with any existing Management Systems – and present a simple, effective, and fully-covered approach to compliance. These templates contain effective tools to simplify the implementation process and demonstrate the effective operation of your Quality Management System.

Designed to save time and effort in the preparation and processing of the Standard by providing fully-fledged documentation – simply providing the assistance of a Consultant, without their presence!

Additional Information

Text:

- Green text are examples only.
- Red text are guidelines which require to be replaced with the correct information.

Document Type and Numbering:

- Document Type is to be determined by the following conventions:
  - POL – Policies
  - PF – Process Flows
  - PRO – Procedures
  - FT – Forms and Templates
  - WI – Work Instructions
- Document numbering is to be in sequential order, with the following convention:
  - (Document Type-Sequential Number) e.g. The first Policy will be labelled POL-001.

Corporate Identity (CI) Manual:

- Your company should have a document in place mandating the following:
  - Naming (exclusive company name)
  - Logo
  - Color palette (color)
  - Corporate font
  - Business card
  - Letterhead
  - Envelop

Logo:

- The Logo is to be placed in the header box (top right-hand corner) of the Word page.
- This image is to be taken as it stands in the Corporate Identity (CI) Manual.

Clause 1: Scope

This section outlines the scope of the Quality Management System. This must be consistent with your quality policy. The intended outcomes should enhance quality performance and fulfil compliance obligations.

Clause 2: Normative References

There are no normative references in ISO 9001:2015. This clause was included to keep the numbering identical to previous editions.

Clause 3: Terms and definitions

This section explains any relevant terms and definitions, which are separated out into four categories:

- Organisation and leadership
- Planning
- Support and operation
- Performance evaluation and improvement

Clause 4: Context of the organization

This section is responsible for detailing the general requirements mandated for an QMS. Within this, an understanding of your organisational context is required. As expected, the quality issues that may affect your organisation are largely dependent on size and industry. The needs and expectations of interested parties who could influence business decisions must also be considered. Through consideration of the context of the organisation, which covers the internal, external, and quality context, all direct and indirect consequences because of quality interaction are to be determined.

Implementation documentation:

- List of Legal Regulatory Contractual and Other Requirements
- List of Internal and External Issues
- Strategic Plan
- List of Interested Parties
- Overall Process Sequence and Interaction

Clause 5: Leadership

This section is responsible for determining the involvement of top management in the QMS. Top management is required, by the standard, to demonstrate leadership and commitment to the QMS. This leadership and support are best shown through the roles, responsibilities, and authorities top management must define. A quality policy is also required to be signed off by top management to demonstrate commitment to business practices that will not cause harm to employees, as well as legal and other requirements as stipulated. From these employees, ISO Champions are to be selected for the system, and are expected to protect workers from harm by determining what resources are required to keep individuals safe.

Implementation documentation:

- Management Responsibility Procedure
- Quality Policy Statement
- QMS Letter of Appointment
- Meeting Minutes Template (To be amended)

Clause 6: Planning

This section of the Standard emphasises the importance of having resources in place to ensure the intended outcome(s) of the QMS are achieved – this is attained through risk identification and analysis. In addition to this, the role of risks and opportunities, as well as how these risks and opportunities will be identified and planned around regarding the QMS. Legal requirements are also to be determined to ensure your company addresses specific actions. The setting of objectives and planning to achieve them must also be defined. In addition to this, it should be noted that ISO 9001:2015 is based on the "Plan-Do-Check-Act" (PDCA) cycle.

Implementation documentation:

- Risk Methodology and Opportunity Procedure
- Risk Assessment Table
- List of Objectives

Clause 7: Support

This section relates specifically to the resources used and needed by the QMS, as well as communication and documentation. As for human resources, adequate assessment of competence, training, and QMS awareness must be demonstrated. The control of documentation relevant to the QMS is also determined. Internal and external communication relevant to the QMS is also to be determined.

Implementation documentation:

- Communications Procedure
- Control of Documents and Records Procedure
- Documents Change Request Sheet (Master Index)
- Calibration Procedure
- Equipment Maintenance Record
- Calibration Log
- Calibration Record
- Monitoring and Measuring of Resources Procedures
- Competence Awareness and Training Procedure
- Performance Appraisal Form
- Induction Checklist for New Employees
- Handover
- Exit Interview
- Training Request Form
- Attendance Register

- Job Description
- Training Matrix

Clause 8: Operations

This section determines how the control of operations will be planned for. For operations with a significant health and safety impact, written processes should be established. It should be specifically noted that these processes must incorporate the solutions identified in clause 6. Emergency health and safety situations must also have plans and response measures in place.

Implementation documentation:

- Client Feedback Form
- Purchasing Control Procedure
- Invoicing Procedure
- Control of External Providers Procedure
- Company Assets List
- Supplier Quality Survey
- Supplier Evaluation Form
- Registry of Complaints about Suppliers
- Petty Cash Register
- Supplier List
- Operational Planning and Control Procedure
- Management of Change Procedure
- Infrastructure and Work Environment Procedure
- Document Change Request Form
- Management of Change Form
- Client Complaints, Resolution and Feedback Procedure
- Customer Requirement Review Checklist
- Registry of Customer Complaints
- Client Complaints Log

Clause 9: Performance evaluation

This section determines how OH&SMS processes (and legal requirements) will be monitored, measured, analysed, and evaluated to ensure compliance. With internal audits, problems and corrective measures will be determined. Furthermore, management must review the QMS to ensure its continuing suitability and adequacy. Management must also determine that the QMS is being used effectively.

Implementation documentation:

- Internal Audit Procedure
- Monitoring, Measurement, Analysis and Evaluation Procedure
- Internal Audit Schedule
- Internal Audit Checklist
- Internal Audit Plan
- Internal Audit Report

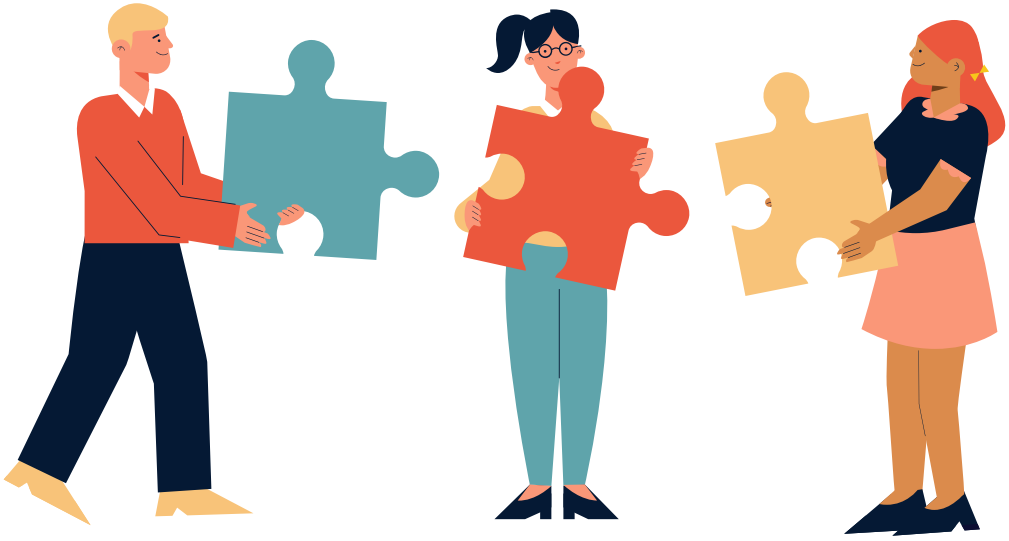
- Opening Closing Meeting Register - Audits
- Gap Analysis Clause Questionnaire
- Management Review Procedure
- Management Review Meeting Agenda
- Management Review Meeting Minutes

Clause 10: Improvement

As for most ISO standards a commitment to continual improvement is important. This section relates specifically to non-conformities that are to be addressed, along with their corresponding corrective and continual improvement actions. Improvement relies heavily on identifying potential issues and using these opportunities to progress processes and reduce quality impacts.

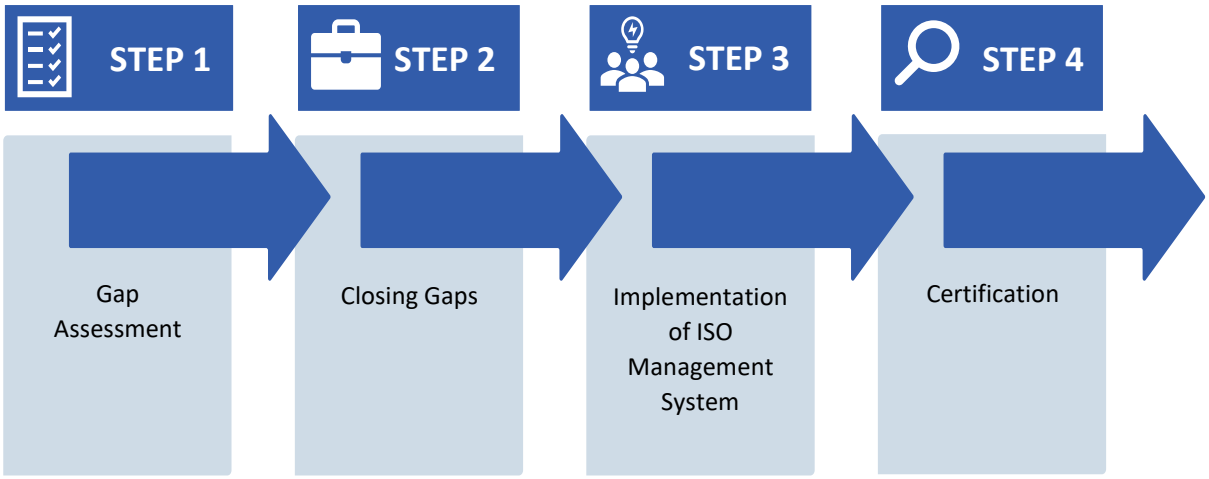
Implementation documentation:

- Non-Conformance and Corrective Action Procedure
- NCR and CAR Report
- Non-Conformance Index
- Supplier Corrective Action Request



CERTIFICATION PROCESS

Any organisation wishing to become ISO certified, needs to implement, and maintain an ISO Management System. The Steps that are recommended for an organisation to become ISO certified are as follows:



Step 1 – Gap Assessment

Why do organisations need gap assessments?

- To understand the organisation's current conformance to the ISO Standard of their choice.
- To identify the relevant documentation and records the organisation might already have which are aligned to the standard and identify how to map it to the ISO Standard's requirements.
- To indicate the amount of work required to conform to the ISO standard and to comply to legal requirements.

What are the outputs of the Gap Assessment?

- A Gap Assessment report indicates the current conformance to the standard and the performance of its Management System.
- An obligation free proposal to assist the organisation in closing the identified gaps to conform to the standard with a project plan for implementation and preparation for certification.

Step 2 -Closing Gaps

- Gaps are closed from a documentation and governance perspective according to the standard.
- Awareness Training for all Staff on the importance of ISO, the benefits of ISO certification and the requirements required per role/ individual in the company.
- Information is gathered to understand the respective roles, responsibilities, processes, and procedures.
- Templates for all documentation are standardised and aligned to the corporate identity.
- The Management system is documented and aligned to the standard's requirements.
- Risk management and the specific plans aligned to the standard are focused on and forms are created to collect data to generate Statistics.

Step 3 – Implementation of the ISO Management System

- ISO management system documentation are implemented and records of at least 3 – 6 months are generated.
- On the job training and Workshops on how to use the management system are conducted.
- Internal audit training and maintenance training are conducted to ensure skills transfer.
- Internal audits (dress rehearsals) are conducted with workshops on non-conformances, corrective actions, the updating of risk assessments and the management system if required.
- A management review is conducted. During the management review an action plan is created to ensure all items, either capital or operational expenditure, are managed and documented.

Step 4 – Certification

Key points to consider when choosing a certification body:

- Is the Certification Body accredited? Logos to look out for are: South African National Accreditation System (SANAS), United Kingdom Assurance Services (UKAS), International Accreditation Forum (IAF), Deutsche Akkreditierungsstelle (DAkkS) and many more.
- There are multiple certification bodies globally, it is important that the certification bodies are accredited and being audited by an accreditation body as mentioned above. This ensures credibility of the certification body and respective clients would want to note that the certification was not attained through the internet or purchased, as each certification body is audited by an accreditation body to the ISO 17021 standard.

Who are the different certification bodies?

- British Standards Institute (BSI)
- TUV Nord
- TUV Rhineland
- TUV Sud
- South African Bureau of Standards (SABS)
- Standard Global Service (SGS)
- Bureau Veritas

What is the difference between Single Site and Multi-Site Certification?

- Single Site Certification –One site/location and its departments (HR, Finance etc) and Processes (Recruitment, Induction, Creditors and Debtors) are audited.
- Multi-Site Certification – Organisations with various sites or offices across the country or world require multi-site certification. The sites are sampled over a 3-year period. The Initial Stage 2 audit will be conducted for all sites.

MAKING YOUR MANAGEMENT SYSTEM WORK FOR YOU

- Top management commitment is key to making this a success.
- Engage the whole business with good internal communication.
- Keep staff informed of what's going on, create a team or assign a champion, as this will increase motivation. This could include a well communicated plan of activities and timescales.
- Motivate staff involvement with training and incentives.
- Think about how different departments work together to avoid silos. Make sure the organization works as a team for the benefit of customers and the organization.
- Review systems, policies, procedures, and processes you have in place – you may already do much of what's in the standard, and make it work for your business.
- Speak to your customers and suppliers. They may be able to suggest improvements and give feedback on your service.
- Train your staff to carry out internal audits. This can help with their understanding, but it could also provide valuable feedback on potential problems or opportunities for improvement.
- Get customer and supplier feedback on current quality management.
- Establish an implementation team to get the best results.
- Map out and share roles, responsibilities and timescales.
- Motivate staff involvement with training and incentives.
- Share knowledge and encourage staff to train as internal auditors.
- Regularly review your system to make sure you are continually improving it.

We are what we repeatedly do. Excellence, then, is not an act, but a habit.

- Aristotle