Quality Management System Guidance

ISO 9001:2015 Clause-by-clause Interpretation

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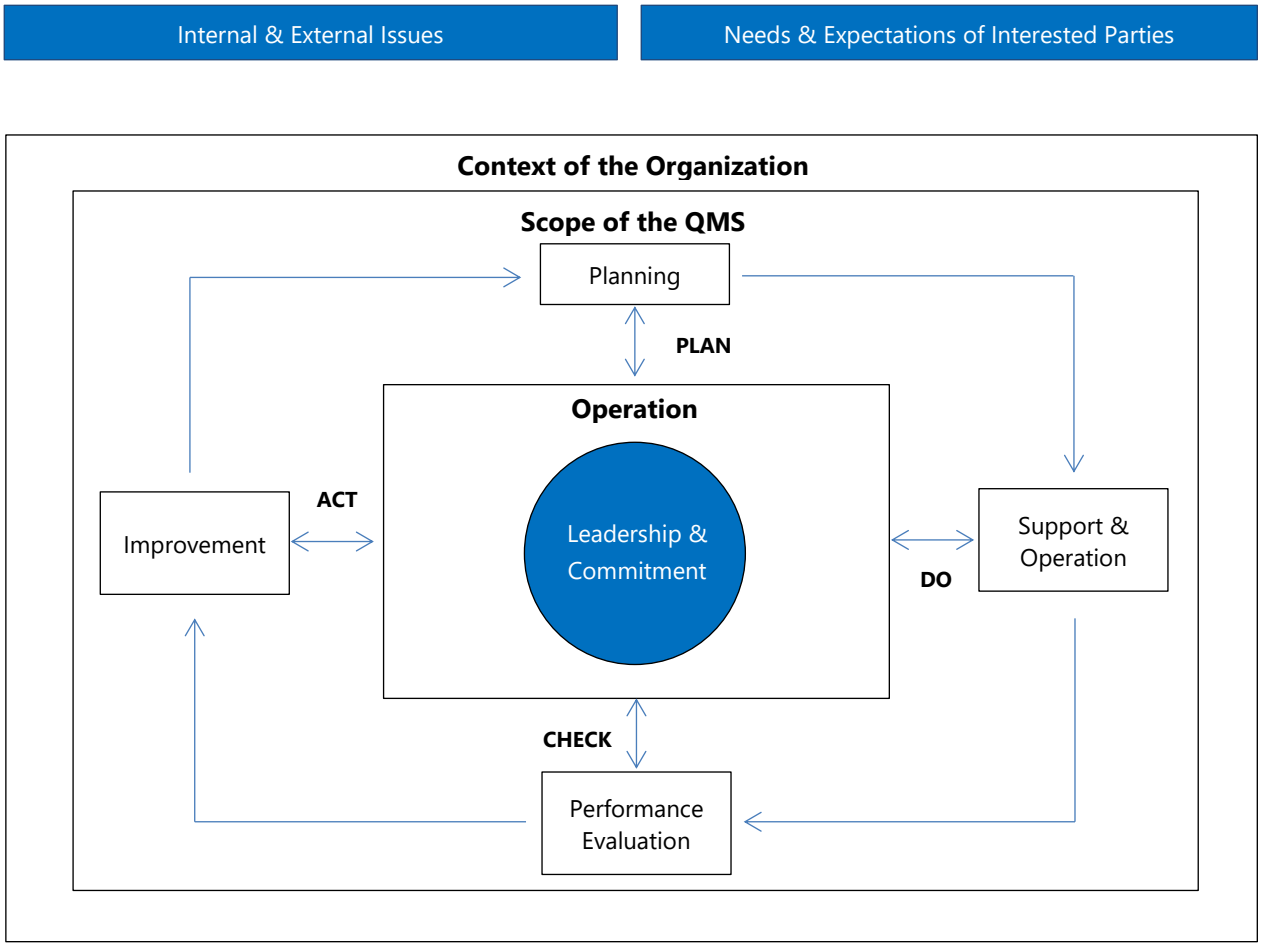
1 Introduction

The purpose of this document is to outline a potential quality management system to meet the requirements of ISO 9001:2015. The quality management system is designed to be implemented to function within current business practices and to serve as an effective tool to help your business grow and improve.

The Figure below illustrates our methodology for the development of your QMS; using the plan, do, check and act process approach, to implement and deliver management system objectives, stakeholder requirements and customer satisfaction.

Figure 1: ISO 9001:2015 QMS & PDCA Interaction



The application of the quality management system is scalable and generic; regardless of the size and type of organization. The elements that form a typical the QMS are the same; please refer to the figure below. The primary goal is to achieve a set of consistent processes that provide a route for enhancing customer satisfaction, mitigation uncertainty and providing meaningful data for continuous improvement activities.

You may decide to keep your current quality management system and simply amend them where necessary. Some of you may take this as an opportunity for a complete revamp of the management system. Both courses of action are entirely reasonable, and this guidance document will guide you through what the essential elements that you need to address in order become certified.

The quality management system includes the processes and procedures required to achieve compliance to quality requirements, as well as, highlight their interaction with other support processes. Top management must take responsibility for leadership, commitment and take active involvement for developing and maintaining the management system. It is necessary to have well defined processes, both operational and support, to be able to realize the product or service. Customer satisfaction has to be measured and analyzed so that the organization can be improved continually.

The implementation of a formal management system is best handled as a specific project that is led by someone with project management experience. Ideally they should be a key member of the organization's management team and have sufficient authority and trust of the personnel involved. In the ideal situation this person will also be the Management Representative, but skills in project management are highly beneficial.

Integration itself is not difficult to implement but rather, the concepts themselves are sometimes difficult to interpret and can therefore be difficult to apply in the real world. For instance, concepts such as non-conformances and corrective actions might seem burdensome at first but the outputs of these concepts will soon be an invaluable source of information that should be used to drive your corporate objectives. In order implement the quality management system, we recommend that you follow the steps in this guidance documents.

1.1 Implementation & Development

Begin with the assumption that you are already doing most of what ISO requires, you probably are! Many people talk about the high cost of implementing management systems but this is a false assumption. If you do it right and understand the standards, then implementation should not be a problem since 75% of your management system is already in place. Here are some initial review tasks to consider:

1. Compare actual performance with external standards, regulations, codes of practice and guidelines;
2. Review existing management procedures;
3. Compare actual operations with internal policies and procedures;
4. Identify policies and procedures dealing with external contracts for services and suppliers;
5. Gather the views of internal and external interested parties;
6. Assess if/how other internal systems can help or interfere with QMS performance;
7. Do a gap analysis comparing what is in place with what ISO 9001 requires.

By implementing a management system like the one detailed in this document, your organization will have the necessary foundation to enact a culture change. It is expected that the culture shift will start during the early development and implementation phase, and by getting involvement and consultation from the employees at this early stage, you can more easily secure buy in by assigning responsibility and utilising their skills, knowledge and experience to help develop the management system.

1.2 Managing the Change

The organizational migration from a pre-certification state to one that operates within the rigors of an ISO based management system is not a casual task. There must be a tightening of how processes are managed and there are often changes in staff interactions, responsibilities and accountability. Such changes are unlikely to succeed without the dedicated support of both the executive and operational management.

The greatest resource of any company are its people, so strategies for managing both real and perceived change, or concerns and attitudes, should be addressed during the initial planning of the QMS. It is likely that during the first few months, Top management will need to positively reinforce its requirements on a routine basis to ensure that staff maintain motivation and do not lapse back into old habits.

Iterative adjustment of new or existing management system documentation should also be expected as staff become accustomed to the requirements and begin to suggest improvements in usability. Instant business or operational improvements may initially be observed. The benefits of a properly functioning QMS are not just restricted to the knowledge that it complies with regulatory requirements but that it has the discipline to manage customer requirements effectively and to mitigate risk.

1.3 Top Management Commitment

Implementation takes time, money and other resources. Make sure you have Top management's commitment before continuing the implementation project. Be sure that Top management are solidly behind implementation of the QMS because without that commitment, the implementation process becomes almost impossible. Top management should demonstrate their initial commitment to the implementation project by the ensuring that:

1. The implementation mandate is communicated and understood;
2. Appropriate resources are made available;
3. An appropriate budget is made available.

Understand why your organization is implementing an quality management system. Is it because a client or the market requires you to register? Is it for internal benefits? Is the motivation coming from top management? Whatever the reasons for implementation, keep them visible during the implementation project as this helps to retain commitment and to maintain focus on the end goal.

It will no longer be appropriate to have one representative driving the QMS on behalf of the rest of the organisation. Top management is accountable for the success of the QMS and as such should lead, promote and direct others to ensure it drives quality benefits.

This is a significant change from the requirements of ISO 9001:2008 where Top management appointed a Management Representative; signed the policies and attended management review meetings. Top management can be one or more people but must have cross-functional influence in order to integrate the QMS with current business processes and to ensure QMS compatibility with your organization's strategic direction.

1.4 Senior Management Engagement

The first step in engagement could be to brief your senior team on the changes. Attendance should be encouraged as failure to transition effectively could mean the loss of the ISO accreditation certificates. However, on a more positive note, for many organizations the new standards could act as a watershed moment where the quality plays a significant part in generating value for your organization. Engagement can be further enhanced by reviewing the quality achievements of your organization.

These are often greater and broader than expected because the initiatives are categorised under economic rather than quality improvement. This realisation builds commitment to do more. By developing engagement

the senior team are more likely to contribute to the other changes such as the context review and stakeholder analysis.

1.5 Implementation Team

Top management should consider creating an Implementation Team to assist in developing the new management system. This decision should be based on the size of the organization or facility that will be implementing the QMS. This team should consist of key individuals from various divisions, departments, and operating work areas from within your organization who are familiar with the facility and the various processes within. Diversity among team members will bring together a pool of expertise and ideas from which to develop and implement the QMS.

One of the key moments in the implementation process is defining the individual responsibility of management and employees for the introduction of different elements into current working process. That is why the most experienced employees from the company should be involved in this process. Following this methodology, a team of experienced and engaged key personnel should be formed at the beginning of the implementation process. The implementation team should include personnel that have the authority to devote resources to the project and to remove roadblocks.

The implementation team should meet on an 'as needed' basis according to the project timeline. When the implementation team meets they must address the items on their task list. Spread out the implementation team meetings along the implantation timeline so you do not have too many meeting at one time. For example, you may want to have the document control team meet early in the project to establish a system to collect and control the documents that will be generated. Whereas, the internal audit team would meet later in the process because audits will not begin until the system is complete.

For certain activities, consulting organizations may provide expertise and guidance, which can be useful in the implementation of the QMS. However, internal staff should be involved throughout the process because they will need to operate the QMS on a daily basis.

1.6 Gap Analysis

Prior to commencing your transition to the new standards, you should answer the following questions; a 'no' indicates a gap and an area you will need to concentrate on.

1. Are Top management engaged and involved with the QMS?
2. In addition to existing quality teams, are other functions involved with the QMS; e.g. procurement, design, production, finance, HR and operations?
3. Is the management system integrated with business processes such as project sign off, competency matrices, procurement requirements and business communications and meetings?
4. Does your QMS take account of the risks and opportunities resulting from trends, macro environmental or big picture issues (political, economic, social, etc.)?
5. Does the QMS consider the impact of changes on your organisation?
6. Do the requirements of internal and external stakeholders help shape the QMS?
7. Is there an existing communication plan (formal or informal) in place?
8. Are robust monitoring and measurement and internal audit procedures in place to ensure quality data is reliable?

9. Are quality requirements imposed upon contractors and suppliers?

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

Your organization may already have in place a management system or parts of a system. If this is the case, you will want to determine how closely your system conforms to the requirements ISO 9001.

The results of a gap analysis exercise will help to determine the differences, or gaps, between your existing management system and the requirements of the standards. Not only will this analysis identify the gaps, but it 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.

The gap analysis output also provides a valuable baseline for the implementation process as a whole and for measuring progress. Try to understand each business process in context of each of the requirements of the standards by comparing different activities and processes with what the standards 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 list now becomes the target of your implementation plan.

Use the gap analysis checklists to compare the requirements of the standard against your organization's existing management system. Each question in the checklist refers to a requirement that must be met in order to comply with ISO 9001:2015.

At the end of this activity you will have a list of activities and processes that comply and a lift of processes that do not comply. The latter list now becomes your action plan. Also consider the effectiveness of what's being practiced on a day to day basis. It is not unusual for an organization to overlook something which needs some work to make it effective. Congratulations, you have just conducted the first audit of your new management system!

1.7 Team Meetings

After the Implementation Team members have been selected, an initial orientation meeting should be held. At the meeting, everyone involved should be informed of the organization's planned implementation as well as team members' new responsibilities.

The initial orientation meetings will get the programme off to a good start, but many more meetings will be necessary. While the primary activities taking place during the early meetings will involve system development and implementation, the Team Leader may also wish to use this time to provide team members with some training.

The Implementation Team should meet on a regular basis to resolve problems and to report progress. Meeting minutes should be documented as they may prove helpful when working with Certification Auditors. In some cases, auditors' questions may be answered by the documented meeting notes.

1.8 Choosing your Registrar

The registrar is a third party certification auditor who will formally assess your management system and issue a certificate if the system meets the requirements of ISO 9001:2015. When choosing a registrar, you should

consider their industry experience, geographic coverage, price and service level offered. The key is to find a registrar who can meet your requirements and who is able to certify against all three standards. For further information regarding accredited certification bodies, please see the following:

Worldwide:	www.iso.org/iso/en/info/ISODirectory/countries.html
Within the UK:	www.ukas.org www.irca.org

Different organizations look at their registrations differently; some organizations prefer to have multiple business units or locations on a single certificate. You can register one location in an organization or you can register the entire organization.

You can even, theoretically, register one part of an individual facility. You should address this issue in your registration scope statement. You should discuss the scope of registration very early in your contact with the registrar, prior to or during the selection process.

The scope of registration and certification will need to reflect precisely and clearly the activities covered by your organization's QMS; any exclusion to non-applicable requirements of the standards should be documented and justified in the QMS manual. No single business related activity should exist outside of the scope.

2 Documented Information

The extent of the documented information will differ from your organization to another because of to the size of organization and its activities, processes, products and services; the complexity of processes and their interactions, and the competence of personnel.

In ISO 9001:2008, the quality manual helped to establish and document the framework of your organization's quality management system while articulating those aspects of the management system to any interested parties. While there is no requirement for a management system manual or even documented procedures in ISO 9001:2015, it is suggested that if your existing documentation adds value, then they should not simply be binned. You will be expected to maintain the integrity of the management system during the transition process.

You do not need to renumber your existing documentation to correspond to the new clauses. It is down to each organization to determine whether the benefits gained from renumbering will exceed the effort involved. Neither do you need to restructure your management system to follow the sequence of and titles of the requirements. Providing all of the requirements contained in ISO 9001:2015 are met, your organization's management system will be compliant.

1. If your system manual fits your business and your customers or regulators require it, keep it!
2. If your procedures are effective and define how your key processes operate, keep them!
3. If the policies and related objectives align with current business strategy, and they are communicated and adding value, keep those too!

Maintain the following as a type of 'documented information':

Maintain the following as a type of documented information	Clause
The scope of the QMS	4.3
Information necessary to support the operation of processes	4.4
Quality policies	5.2
Risk and opportunities that need to be addressed	6.1.1
QMS objectives	6.2
Documented information required by ISO 9001:2015	7.5.1a

Retain the following as a type of 'documented information' as a record:

Retain the following as a type of documented information as a record	Clause
Documented information to the extent necessary to have confidence that the processes are being carried out as planned	4.4
Evidence of fitness for purpose of monitoring and measuring resources	7.1.5.1
Evidence of the basis used for calibration of the monitoring and measurement resources (when no international or national standards exist)	7.1.5.2
Evidence of competence of people doing work under the control of the organization that affects the performance and effectiveness of the QMS	7.2
Evidence of communications to external parties and interested parties	7.4.1

9.1.3 Analysis & Evaluation

This requirement is **comparable** to ISO 9001:2008 Clause 8.4 - Analysis of Data. You should expect to see that the organization has developed a process (method, techniques, format, etc.) to identify, collect and analyze and evaluate data and information from both internal and external sources (i.e. quality records, monitoring and measuring results, process performance results, objectives, internal audit findings, customer surveys and feedback, 2nd or 3rd-party audit results, competitor and benchmarking information, product test results, complaints, supplier performance information, etc.).

This 'input' (information and data) should reflect upon the adequacy, suitability and effectiveness of the quality management system and its processes. The 'output' (result of the analysis) must provide information (understanding, insight, awareness, confidence, knowledge of, etc.). The analysis output must provide insight to:

1. Customer satisfaction and perception;
2. Product conformance;
3. Process performance;
4. Product and process characteristics;
5. Trends in products and processes;
6. Opportunities for preventive action;
7. Suppliers and subcontractors.
8. Need for corrective action;
9. Opportunity for improvement;
10. Competition.

The requirements of Clause 9.1.3 interrelate with those in clauses:

1. Management review input;
2. Improvement;
3. Corrective action;
4. Risks and opportunities.

Furthermore, any record with data that is an established part of the QMS may be considered relevant for analysis. Records are evidence of system performance and should be analyzed for potential improvements.

9.2 Internal Audit

This requirement is unchanged from the requirements of ISO 9001:2008. Your organization should establish an internal audit programme to cover all requirements of the standards. In addition, you should ensure that consideration is given to the status and importance of the processes that comprise the audit programme and the results of previous audits. Objective evidence should demonstrate information of concerning the effective implementation the audit programme, as well as a sample of audit results.

In ISO 9001:2008, the purpose of the internal audit is to 'determine whether the management system conforms to requirements and is effectively implemented and maintained', i.e. *to actually make the judgment*. In the 2015 version of the standards, the purpose of the internal audit is to simply '*provide information*' as to whether this is the case. Subsequent determination is now undertaken by relevant management, e.g. during management review meetings.

9.2.1 Internal Audit Programme

Planning the internal audit programme, whilst taking into account process status and importance, is one of the most disregarded requirements of ISO 9001. Use the process status and importance tracker to help determine which of your processes and procedures should be audited more frequently than others by entering a score to rank various process attributes.

The resulting scores are highlighted to indicate whether the process requires more frequent auditing based on its ability to affect the customer and how well it is performing. This is a great way to mathematically substantiate your audit schedule. You should then schedule processes with high, red scores for additional audits, perhaps or three or even more times per year.

Status

You should consider process status in terms of maturity and stability; a more established, proven process will be audited less frequently than a newly implemented or recently modified process and should receive a lower status score. Conversely; processes which are not performing to the planned arrangements, should be assigned a higher status score.

Importance

You should consider process importance as the degree of direct impact that process performance has on customer satisfaction; i.e. could the process provide the customer with non-conforming product? Support processes should be given a lower ranking than the manufacturing/service provision processes. In addition, the results of previous audits should be considered too. Processes that have been audited recently that have shown effectiveness and improvement should be audited less frequently.

Quality Ranking

Consider how a failure in quality and attributes could affect your customers in terms of providing non-conforming product. In fact, why not ask your customers which attributes could affect them the most, as this method provides a great way to engage with them and to objectively justify the audit programme to Top management.

Customer Complaints

Simply put, enter the actual number of complaints in the relevant cell that is related to the process. Customer complaints are ranked very highly in terms of seriousness and will elicit a red warning on the total score heat map to highlight that process as requiring greater audit scrutiny.

Corrective Actions

Include the number of open corrective actions in the relevant cell that is related to the process. The corrective actions should be included and must cover all those that were raised internally or externally. External corrective actions rank higher in terms of importance than internal corrective actions. External corrective actions might arise from customer audits, registrar audits or from other stakeholders.

9.2.2 Internal Audit Checklists

The audit checklist is just one of the many tools which are available from the auditor's toolbox that help ensure your audits address the necessary requirements. The checklist stands as a reference point before, during and after the audit, and will provide the following benefits:

1. Ensures the audit is conducted systematically;
2. Promotes audit planning;
3. Ensures a consistent audit approach;
4. Actively supports your organization's audit process;
5. Provides a repository for notes collected during the audit process;
6. Ensures uniformity in the performance of different auditors;
7. Provides reference to objective evidence.

We have provided you with three different audit checklists and each checklist allows you to determine the extent to which your management system conforms to the requirements by determining whether those requirements have been effectively implemented and maintained. The templates will help you to assess the status of your existing management system and identify process weakness to allow a targeted approach to prioritizing corrective action to drive improvement.

1. Audit checklist metrics dashboard graphically displays status attributes;
2. Quickly identify and target system weakness with heat maps;
3. Real time charts display audit result data - ideal for reports or presentations.

The dashboard provides fast and reliable access to system and process metrics, precluding the need to know where all performance data is stored, or for having to locate the metrics champion for current data. It also reduces the likelihood that data is lost when metrics owners change or leave the company and reduces the learning curve for new metrics owners.

1. Clearly illuminates under-performing metrics for prompt management attention;
2. Provides a unique management ally during internal and external audits;
3. Improves meeting efficiency by segregating metrics.

Auditors should not necessarily expect to find a documented internal audit procedure in place. However, they must be able to access documented information confirming the implementation of an audit programme by the organization. Documented information must also be available to evidence the results of audits. When designing the audit programme you should ensure that customer feedback, organizational changes, and risks and opportunities have been brought into consideration.

9.3 Management Review

9.3.1 General

Top management must periodically review the QMS to ensure its continuing suitability, adequacy, and effectiveness. The frequency or intervals of the Top management's formal review must be defined in the QMS. The management review must address the possible need for changes to policy, objectives, targets, and other elements of the QMS. The management review process must ensure that the necessary information is collected ahead of time to allow management to effectively carry out this evaluation. Information that must be reviewed includes:

1. Minutes from previous management reviews;
2. The policies, objectives and targets;
3. Results of QMS and process audits;
4. The extent to which objectives and the numeric targets were met.