Mastering ISO 9001:2015
A Step-By-Step Guide to the World’s Most Popular Management Standard
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A Step-By-Step Guide To The World’s Most Popular Management Standard

Gregory Peckford
This book is dedicated to my amazing wife and best friend Aileen, for her support and unwavering belief in my ability to accomplish my goals even when my own vision is less than clear.

And to my parents Tom and Marie who have always been my biggest fans.
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Welcome to Mastering ISO 9001:2015 where you will learn the concepts and fundamental principles of the world's most popular, and widely utilized quality management standard. I created Mastering ISO 9001:2015 to help professionals elevate their careers and organizations improve business performance through the use of quality management. One of the key decisions I made in my own career, one that has been instrumental in my professional development, was learning the ISO 9000 group of standards and developing that knowledge into a thriving career in quality management.

But you do not have to be a quality management professional or auditor to take advantage of the information contained within this book. ISO 9000 can help to improve your own company's processes on any level, whether you're the CEO or a department manager. ISO 9000 can also provide you with valuable tools to make you a better decision-maker within your organization. For me, becoming proficient in the ISO 9000 family of standards has allowed me to progress in my career, not only as a quality management professional, but also as a corporate and project level manager in multiple industries. ISO 9000 allowed me to expand on the valuable technical knowledge I had developed throughout my career and adapt those skills to any situation.

In this book you will be introduced to the ISO 9000 family of standards, and learn the benefit that this knowledge can have on your business, organization and your career. We will discuss the 7 fundamental Quality Management principles that form the basis for the ISO 9001:2015 standard. We will cover the concepts and importance of process approach and the Plan-Do-Check-Act cycle when developing and implementing a quality management system. Also, we will discuss the concept of risk-based thinking, and the
importance ISO 9001:2015 places on building this into the whole management system in order to better manage risk and take advantage of possible opportunities. Now that the newest version of the ISO 9001 standard has been released we will discuss the transition process from the 2008 to 2015 revision. And of course, we will go through the ISO 9001:2015 standard in detail, clause by clause, so that you will walk away with a solid understanding of this widely utilized and diverse quality management system criteria, which will allow you to not only improve business performance, but also increase your professional value and diversify your career potential.

So, just what are the ISO 9000 series of standards and what are the benefits of incorporating these guidelines into your business or professional toolkit? ISO 9000 is a set of globally recognized standards for quality management. The standards are purposely generic in nature, even more so with the latest 2015 revision, as they are meant to apply to any industry or organization regardless of size and product or service offered. So basically, if you understand the principles of the ISO 9000 series of standards, you should be able to apply those concepts to any business. Many people see ISO 9001 as a manufacturing standard, but due to its generic nature, it is much more than that and can be implemented in any product or service-based business. And now with the release of the ISO 9001:2015 revision, this diversity has been made even more apparent.

So why is ISO important? What are the benefits for businesses in implementing these standards and for individuals in learning and becoming proficient in this knowledge? ISO standards provide businesses with a valuable toolkit to not only improve quality, but also increase efficiency and productivity in their processes. It provides a guideline to enhance customer satisfaction, reduce risk, take advantage of opportunity, and in turn increase sales and profitability. For the individual, proficiency in the ISO standard can provide a skill set to help your organization implement strategies to
reach these desired goals and advance your professional value. I think it's pretty clear that if you are able to provide valuable input and improve your organization's processes, as well as help them become more effective, then your career can only prosper.
CHAPTER 1

ISO 9000 SERIES OF STANDARDS

“If you don't drive your business, you will be driven out of business.”
-B. C. Forbes

So we touched on what the ISO 9000 series of standards are as a whole, now I would like to go into the individual standards that make up the 9000 family and how they can be used as an integrated set for maximum effectiveness.

- ISO 9000:2015 covers the basic concepts and language used in the standard by providing the terms and definitions found throughout.

- ISO 9001:2015 sets out the requirements of a quality management system and is the only standard in the ISO 9000 family that can be certified or audited to. ISO 9001 is the main document and contains the 10 relevant clauses that make up the standards criteria – and is what we will focus on in the majority of this book. Keep in mind that ISO 9001 is a generic standard and is not intended to dictate how a business is to be run. Implementation is up to the organization and is based largely on the company's scope of business. What's
important is that the requirements are met in order to obtain certification or to effectively benefit from its implementation.

- **ISO 9004:2009** provides guidance over and above the requirements included in ISO 9001 and also contains guidelines for self-assessment and is not intended for certification purposes. ISO 9004 focuses more on increasing the effectiveness and efficiency of a quality management system.

- **ISO 19011:2011** provides a guideline for conducting and managing internal and external audits of a quality management system. This is a great resource for anyone involved in the audit process.

### Seven (7) Quality Management Principles

ISO 9001 is based on 7 quality management principles which are defined in ISO 9000:2015 and ISO 9004:2009 and are intended to provide senior management with a framework for improving performance within the organization. Let's take a look at each one of those principles right now.

1. The first quality management principle is *customer focus*, and it maintains that organizations should understand current and future customer needs and requirements and always strive to exceed expectations. I think it goes without saying that if you can focus on the customer's needs and constantly find ways to improve how you deliver on those needs, you will see increased revenue and repeat business.
2. The second principle is *leadership*; we all know that strong leadership is key in the success of any business. Leaders in an organization set the direction and create an environment for people to buy in and get involved and be motivated in achieving established organizational objectives. This promotes unity and effective communication.

3. The next quality management principle is *engagement of people*; and this ties in with the previous principle, which was leadership. Leaders set the tone, but the benefits are truly apparent when you have full involvement of the people at all levels of the organization. Having this involvement promotes innovation, creativity and accountability among other benefits.

4. The fourth principle is a *process approach*; and we will discuss this in more detail coming up, but by managing resources and activities as a process, a desired outcome can be obtained far more efficiently and effectively while improving cost and achieving predictable and consistent results.

5. Next we have *improvement*; which unfortunately is highly overlooked by many organizations, but should be a high-focus area and a constant objective for improvement at all levels of organizational performance.

6. The 6th quality management principle is a key element of effective management and that is *evidence-based decision making*; making informed, fact-based decisions, through careful analysis that can be backed up with data and available information.

7. And the final quality management principle that forms the basis for the ISO 9000 group of standards is *relationship*
management; realizing that the organization and its external partners must have an interdependent relationship that promotes value. Both have a stake in the game and must work together to achieve consistent and yet flexible results to create value for both parties.

So these are the 7 principles for quality management that structure the ISO 9001:2015 standard, and although these are not auditable requirements, it is wise that an organization build off of these principles when developing a quality management system.

Process Approach

The process approach has always been a very important part of the ISO 9001 standard and this has not changed in the 2015 revision. ISO strongly encourages organizations to adopt a process approach when developing and implementing a quality management system, and asks that top management exercise leadership by promoting an awareness of this approach. But what exactly does this mean? A process is an activity or set of activities that uses resources and is managed in order to enable the transformation of inputs into outputs. The process approach is a management strategy; when management chooses to implement a process approach, it means that they manage and control the processes that make up their organizations, the interactions between these processes, and the inputs and outputs that tie these processes together as a coherent system. It is essential that processes be monitored and measured for effectiveness throughout all stages.

So what does applying the process approach in a quality management system enable? It aids organizations in the better understanding of requirements whether they are customer, contractual or regulatory, and the importance of maintaining
consistency in meeting those requirements. It helps organizations view its processes in terms of requirements, and a means to meet those specific requirements. A process approach helps to ensure process performance is achieved effectively and continues to meet its desired goal efficiently and consistently, and helps organizations improve on process performance based on the evaluation of data and information gathered through continuous monitoring activities. (See Figure 1)
Figure 1: Elements of a process
Plan-Do-Check-Act Cycle (P.D.C.A.)

In addition, ISO recommends applying the PDCA or Plan-Do-Check-Act methodology in the development of a quality management system and its processes. This methodology provides a repeating cycle of action and monitoring that promotes continuous improvement and effective process management. The four-step cycle consists of the following:

- **Plan** - Planning your objectives, activities and resources necessary to develop effective processes that will meet requirements.

- **Do** - Do what you planned in the previous step and implement the processes.

- **Check** - Check or monitor the process for effectiveness against established requirements and record the results.

- **Act** - Act on the data collected while monitoring the process and make the required adjustments to continually improve the process.

Continue to repeat this cycle to maintain process effectiveness, as business needs change.
In this chapter we will discuss the concept of risk-based thinking, and the importance ISO 9001:2015 places on building this into the whole management system in order to better manage risk and take advantage of possible opportunities. Also, in Chapter 2 we will discuss the transition process from the 2008 to 2015 revision, and what that transition means for an organization.

Risk-based thinking

One of the key changes in the 2015 revision of the ISO 9001 standard is the addition of risk-based thinking. Making risk inherent in all aspects of a quality management system as opposed to treating preventive action as a separate component to be considered in isolation. Of course, risk has always been a factor in ISO 9001, but now it has been given more of an integral role in the latest revision, and organizations are now required to plan and implement processes to address risk, and it is something that should be considered in all
aspects of an organization's quality management system. Something to note is that with the addition of risk-based thinking, the section on preventive action (Section 8.5.3 of ISO 9001:2008) has become redundant and removed in the 2015 edition. Organizations are encouraged to consider risk in terms of negative and positive outcomes. It is common sense that you would want to identify negative scenarios and plan to mitigate against them, however it is equally important to identify possible opportunities that may arise and take advantage of those opportunities for positive growth.

Let’s look at this from a more practical perspective. Let’s say for example, you are planning a family vacation, by implementing risk-based thinking, you would consider the risks involved prior to booking your trip:

➢ You might decide against purchasing flight insurance in order to reduce the cost of your plane ticket. Is the risk of cancellation and losing the cost of the ticket acceptable?
➢ What is the weather generally like in your city of departure and arrival at the time you plan to travel?
➢ Is there a chance of severe weather that could affect your travel plans?
➢ What about illness? Is there a risk of disease or sickness that is common to the area you plan to visit? Are there vaccinations available to help prevent contracting such an illness prior to taking your trip?

Alternatively, there are possible opportunities to consider such as:

➢ If you are flexible with your travel dates, you could take advantage of flight, or hotel sale prices that are only available at certain times.
➢ What activities, or special events are taking place, which you could attend if you are aware of them in advance?
These are things we would normally consider in our daily lives, so why would we not take the same approach in business?

So now that we understand the concept of risk-based thinking, how do we incorporate this into a quality management system?

I. The first step is to identify risks and opportunities dependant on the context of the organization, and scope of the QMS. Until risk and opportunity have been adequately identified, it is impossible to factor this into process development.

II. Once identified, organizations can begin to assess and understand these risks and opportunities, and make determinations on what is acceptable and what is unacceptable, as well as the opportunities to be taken advantage of – planning actions to address these risks and take advantage of possible opportunities.

III. Determining the options available in order to adequately mitigate risk factors and the necessary steps required.

IV. Then take action, and implement the strategies developed during the planning stage, and incorporate these actions into business processes.

V. Lastly, organizations must assess the effectiveness of these actions, and learn from the collected data in order to refine processes for continuous improvement.
Revision changes and making the transition

OK, so let's take a look at some of the key changes with ISO 9001:2015. On September 23, 2015, ISO released the latest revision to the ISO 9001 standard. So I thought it would be a good idea to give you a brief explanation of the changes, and what effect those changes will have on organizations, and the people who have the responsibility of implementing, managing and auditing the new standard. While many of the concepts from the 2008 version of the standard remain, there are some significant changes, and additions, to the 2015 edition, which we will take a closer look at right now.

- One of the more obvious changes to the 2015 revision is in the look and structure of the standard itself. In an effort to maintain consistency across multiple ISO management systems, the latest revision takes on the new Annex SL format that is shared by other standards such as ISO 14001 Environmental Management Systems. Both the ISO 14001, and new ISO 9001:2015, share the same clause structure, to allow organizations the ability to implement, and integrate multiple management systems more easily and effectively.

- As discussed earlier, the ISO 9001:2015 revision promote the incorporation of risk-based thinking within the management structure of the organization. This is not to be confused with a stand-alone risk management procedure, but the incorporation of risk awareness and identification throughout the system as a whole.

- Top management are now required to develop processes that allow foresight and planning for possible risk factors that may have a negative impact on process and performance, as well
as identify and take advantage of possible opportunities. As mentioned earlier, with the addition of risk-based thinking, the section addressing preventive action, sub-clause 8.5.3 in ISO 9001:2008, has been deemed redundant, and therefore removed from the 2015 revision.

- Another change in ISO 9001:2015 is greater emphasis on Leadership, and Management Commitment. The new standard is intended to promote integration and alignment with business processes and strategies. With this integration, top management now have more responsibility in taking on a proactive role in the health and promotion of the quality management system. The requirement for a single point of contact or management representative regarding the QMS has been removed, and a new section on leadership has been added to better emphasize a greater involvement from the leadership team.

- Another notable change is the replacement of the term “product” with “product and services”, which is intended to better address service-based organizations.

- Along with the change in the term “product”, the 2015 revision also replaces the common terms “documents” and “records” with “documented information”. Organizations are required to retain documented information as evidence of the implementation of the audit program and audit results.

- ISO 9001:2015 has no specific requirement for documentation of procedures, leaving it up to the organization to define their own needs for documentation, while taking into consideration client and regulatory requirements.
• In ISO 9001:2008 there were 6 required documented procedures that every organization must have as part of its QMS. This is no longer a requirement in the 2015 edition.

This is not an exhaustive list of amendments to the new version of the standard, but a high-level look at the new content and structure of the newly released standard.

The new ISO 9001:2015 standard has been formally released for public consumption and implementation; however, organizations are not expected to be compliant to the new changes immediately. Organizations have been granted a 3-year transition period before compliance to the new standard is required, for those that maintain certification to ISO 9001:2008. So don't throw out your copy of the existing 2008 standard just yet! Organizations and quality professionals are urged to become familiar with the new requirements, and perform gap analysis of their current system to determine the steps required for eventual implementation of the new 2015 revision by September 2018. Once the gaps have been identified, it is important to develop a plan for closing the gaps, and determining the steps and resources required to meet the requirements of the new standard. It is also imperative to provide training and awareness of the new requirements, and actions necessary to meet those requirements, so that all personnel are on the same page and moving in the same direction towards the organization's goals – and of course, implementation of the plan, and updating of the existing QMS to meet the requirements of ISO 9001:2015.
CHAPTER 3

“Markets change, tastes change, so the companies and the individuals who choose to compete in those markets must change.”
-An Wang

In this chapter, I will introduce you to the standard content itself, and talk about the first 3 clauses of the ISO 9001:2015 standard. These first sections are very short with minimal content, and essentially provide a reference to other documents included in the ISO 9000 family that have been referenced, and form as support for the standard itself. It also provides the scope of the standard, and lays out the general purpose, and where and when the standard applies to an organization.

So let's get started!

Clause 1: Scope

The first clause which defines the scope of the standard itself as specifying the requirements for a quality management system that enables an organization to demonstrate its ability to consistently provide a product or service that meets customer, regulatory and statutory requirements, and aims to enhance customer satisfaction through the effective application of the system, processes for
continuous improvement of the system, and assurance of conformity to requirements. This should not be confused with the scope of a quality management system itself, which should be based on the nature of the organization's products and services as well as their realization processes, the result of risk assessment, commercial considerations, and contractual, statutory and regulatory requirements.

Section 1 also highlights the broad range and flexibility of the ISO 9001 standard, stating that all requirements of the standard are generic, and applicable to all organizations regardless of type, size or product & service offered. This diversity in application has been made even more apparent in this latest 2015 revision of the standard by becoming less prescriptive, and highlighting the applicability to service-based organizations, as opposed to product alone. So ISO 9001 is no longer just for the manufacturing industry, but can now be more effectively moulded to fit all types of organizations and industries, regardless of the product or service they offer.

It is also important to note that in the ISO 9001 standard, the terms “product” and “service” only apply to those products or services intended for, or required by a client or customer, and that statutory and regulatory requirements can also be referred to as legal requirements.

Clause 2: Normative References / 3 Terms and Definitions

We will not spend too much time on the next two clauses of the ISO 9001 standard – normative references and terms and definitions – as they simply point us to the reference document ISO 9000:2015 Quality Management System Fundamentals and Vocabulary, which contains terms and definitions, and is normatively referenced throughout the standard. This is in no means meant to minimize the
importance of the ISO 9000:2015 document, which is indispensable for its application, and should form part of the QMS implementation process. So if you have not obtained a copy of ISO 9000:2015, I would highly suggest you do so.

In the next chapter we will discuss clause 4 (Context of the Organization). In this section, we will talk about understanding the organization and its context, understanding the needs and expectations of interested parties, determining the scope of the quality management system, and the quality management system and its processes.
CHAPTER 4

CLAUSE 4: CONTEXT OF THE ORGANIZATION

“If you're trying to create a company, it's like baking a cake. You have to have all the ingredients in the right proportion.”
- Elon Musk

This chapter, beginning with Clause 4, is really where the essentials of the 9001 standard begin, and where we really get into the applicable requirements that assist in the development of processes that help the organization reach its strategic objectives and produce products and services that meet client, and regulatory requirements in an effective, efficient, and consistent manner. The implementation of a quality management system is a strategic decision influenced by the context of the organization. Having a clear understanding of that organizational environment is essential to establishing and implementing a quality management system and determining the scope of that system within the organization.

Section 4 – Context of the Organization – is a new requirement in ISO 9001:2015, stating that an organization must consider both the internal and external issues, as well as all interested parties, that are relevant to its quality management system, and that may have an impact on achieving the intended results of the QMS. I will emphasize that it is important to limit the focus to issues and
interested parties that have a direct influence, or relevance, on the organization's quality management system, in order to keep things manageable. ISO 9001 does not tell organizations how to operate, but provides a guideline for organizations to develop and implement a QMS, and its applicable processes, that is suitably adapted to its specific needs within the context of their particular business and requirements.

It’s important to point out that this is the first time in the new standard that we encounter risk-based thinking when determining the context of the organization. Internal and external issues can come in the form of negative or positive factors, and both should be considered and evaluated.

Let's take a closer look at the following sub-clauses of Section 4, Context of the Organization, which are:

● 4.1. Understanding the organization and its context;
● 4.2. Understanding the needs and expectations of interested parties;
● 4.3. Determining the scope of the quality management system;
● 4.4. Quality management system and its context

4.1: Understanding the organization and its context

In order to develop and maintain an effective quality management system that truly adds value and is aligned with the strategic direction of an organization, management must first determine and understand all of the internal and external issues that have an effect, or possible effect, on the QMS, and are relevant to its purpose, as well as the
success of the corporate strategy. Significantly also, management must determine and understand the internal and external issues that have an effect on its ability to achieve intended results. These issues can stem from any number of sources, and is dependent on the organizational environment, and the type of product or service they provide, as well as the socioeconomic conditions they operate in.

So what exactly does this mean? It means that the organization as a collective entity must do some soul-searching, and perform self-assessment activities that will reveal very important information about who they are as a company, what things they do well, as well as what areas they are performing poorly. They must objectively evaluate the factors that affect how they serve their customers’ needs effectively, and ensure business success. This self-introspection is not something that all, or most organizations perform well, let alone develop processes for, as it can be difficult to remain unbiased and objective when looking inwards. But this activity can provide massive value to the success of the organization's quality management system. This is exactly what this new section of the ISO 9001 standard requires, and it is no surprise that ISO made this the leadoff section for the standard, as the outputs from implementing the concepts of Clause 4.1, should be used as inputs for all other activities required by the standard.

A good model for this type of internal and external environmental assessment could be the SWOT analysis method.

- By evaluating **Strengths** - characteristics of the business that give it an advantage over others.

- **Weaknesses** - characteristics that place the business at a disadvantage relative to others.
• **Opportunities** - elements that the business could exploit to its advantage.

• **Threats** - elements in the environment that could cause trouble for the organization.

ISO does not require or imply that this method be used, however, it could be a valuable tool for this purpose.

➢ Organizations must consider *positive and negative factors, or conditions, regarding internal and external issues.* As I just mentioned in the SWOT analysis example, it is important to capture the possibility of opportunity which the organization can exploit, and not have a narrow focus on negative issues alone. Of course it is important to recognize issues that could negatively impact business, but it’s equally important to take advantage of opportunities that could present strategic advantages.

➢ The standard also requires that organizations *monitor and review the information relating to its internal and external issues* that may have an impact on the organization's ability to implement and maintain an effective quality management system, as well as achieve intended results.

➢ There are many external factors that could have an impact on the success of an organization, and some will carry more weight than others. Organizations should consider the issues arising from areas that have the greatest impact on their own business. Some examples of these external areas are;

  • Legal - what laws are in place both in the area the organization operates, as well as other areas that have
an impact on its business, such as where the product they produce will be used, or services conducted.

● Technological - what technologies exist that can assist the organization in better management and operation, and what new technologies are on the horizon?

● What is the level of competition in the current market?

● What are the cultural, social and economic environments that will have an effect on the organization and its products and services, whether they be national, international, regional, or local landscapes?

There are also many internal issues to be considered that may arise from areas such as;

● The values that people within the organization bring to the workplace,

● The cultures representing those people,

● The culture of the organization itself as well. What type of culture does the organization wish to develop and convey to its personnel and customers? And how do they nurture this culture?

● What collective knowledge and expertise exists within the organization from experience of its personnel, to past performance and operation of the organization itself. What knowledge and experience will have to be acquired to reach its strategic objectives?
Again, understanding of the internal and external environment that an organization operates within is a vital part of the success of its quality management system, and ultimately the success of its business.

This is a brand new clause in the ISO 9001:2015 standard, which holds many intangible concepts that some organizations may struggle with at first, but are essential to any hope of longevity in business.

4.2: Understanding the needs and expectations of interested parties

ISO 9001:2015 requires that organizations determine requirements relating to its customers. This would seem like a pretty obvious activity. Determine who your customers are, find out what they need, and then provide a product or service to satisfy that need. Business 101. But what might be a little less obvious, is the importance of developing a process for identifying and determining the requirements relating to what ISO 9001:2015 refers to as interested parties.

- Interested parties are those bodies, whether internal or external to the organization, who are relevant to the quality management system, that may have an effect, or potential effect, on the organization's ability to produce intended results. Or alternatively, that may be affected by the operations, or products and services, produced by the organization. So the first step in this process is to identify who those interested parties are for a particular organization. These parties will differ for each organization, and are dependent on the nature of the products and services offered.
Once the relevant interested parties have been identified, it’s up to the organization to develop processes to determine the requirements of those specific interested parties, as well as any possible impact the operations of the organization may have on those interested parties.

Take this example to give you an idea of the types of interested parties organizations may identify, and what requirements or impacts may be considered. If an organization decides to ramp up production to meet a client need, while the internal processes may be up to the task, are vendors and suppliers capable of meeting the new demand? Are shipping companies capable of meeting the advanced delivery and volume schedules? Are employees able to meet the additional man-hours while meeting regulatory or union requirements? ISO 9001:2015 does not specify how an organization goes about determining these requirements or identifying potential interested parties. It’s the responsibility of the organization to develop these processes based on the relevance to its own QMS.

Organizations are required to monitor and review this information, as these interested parties can have a potential effect on the ability to produce products and services that consistently meet customer and regulatory requirements.

ISO 9001 does not require that organizations retain documented information or records of the process or outputs involving interested parties, but it would be difficult for an organization to show compliance to the clause, or to perform adequate review, without some form of documentation.
4.3: Determining the scope of the quality management system

We discussed the scope of the ISO 9001:2015 standard in the previous chapter. This was in regards to the standard itself, and when the ISO 9001 requirements are applicable to an organization and its quality management system. Basically, who would benefit from establishing a QMS that is in conformity with the ISO 9001 requirements?

In this section, we will discuss scope as it applies to establishing the boundaries, or the areas of the organization that are to be included and controlled within the quality management system, as well as the applicability of the ISO 9001:2015 standard requirements within those boundaries of an organization's QMS. Clear definition of the scope is vital to the successful implementation of a quality management system.

ISO requires that all requirements of the ISO 9001:2015 standard that are applicable to the organization's scope be applied. However, there are exceptions. For example, Clause 4.1, understanding the organization and its context, would be applicable to all organizations. However, Clause 8.3 (Design and development of products and services) which we will discuss in Chapter 8, may not apply if the organization does not perform design and development activities as part of their business process. Obviously then, they would not develop processes and controls for these activities. This requirement could then be justifiably excluded from the scope of the QMS. It's important to keep in mind that excluding certain requirements or sections of the standard, just because it is convenient, is not valid justification when it comes to certification for the ISO 9001:2015 standard. Any exclusions pertaining to requirements must have sound justification for the exclusion, as well as ensure that the exclusion
does not affect the organization's ability to meet conformity to requirements or the enhancement of customer satisfaction.

- In order to effectively determine the scope of its QMS, organizations must consider the external and internal issues as discussed previously in section 4.1, understanding the organization and its context.

- Also, there is the need for organizations to understand the requirements of all relevant interested parties as referenced in section 4.2. This information is a required input to defining the scope of the quality management system as organizations must determine if, and to what extent, the QMS extends to processes developed to address internal and external issues, including risk and opportunity, as well as the requirements of its interested parties. The scope of the QMS will differ for all organizations, as there are many factors to consider which are specific to the context of a particular business. With information gathered from the implementation of processes outlined in sections 4.1 and 4.2, organizations are now much better equipped to define the boundaries of their quality management system. Referencing back to Clause 4 (Context of the Organization) is a common theme throughout the ISO 9001 standard, as this is essential for developing an effective quality management system.

- Another consideration when determining the scope of the QMS is the actual products and services offered by the organization. The organization must determine if all products and services produced will be included in the scope of the QMS, or if the scope will be limited to select products and services alone, and others excluded.
Organizations must ask important questions of themselves in order to accurately define the scope of their quality management system. What areas of the organization should be incorporated under the QMS umbrella? Are all of the products and services that the organization produce going to be included or just a select few? Are all departments required to operate under the requirements of the QMS, such as finance and HR for example, or is the QMS scope limited to operations and production alone? Of course it is better to make the QMS as broad as possible and include as much of the organization and its products and service as possible. But this is a decision that has to be made in the best interest of the organization.

ISO 9001:2015 requires that the scope of the QMS be maintained and available as documented information, and must clearly determine and outline the boundaries of the quality management system. It must document and identify the products and services included within the scope of the QMS, as well as identify any products and services that have been excluded. This documented scope statement must also explain any justification for requirements of the standard that the organization has determined inapplicable to the scope of its QMS, and the requirements of the ISO 9001:2015 standard. This is required so that the scope of the quality management system is clear to all who have involvement with the processes and outputs of the QMS – not only those within the organization itself, but also to its stakeholders and relevant interested parties.

Plus, in the case of certification to the standard, it must be clear to certification auditors that the organization has adequately defined the scope of the QMS, and that all applicable requirements are being met.
4.4: Quality management system and its processes

Organizations are required to establish, implement, and maintain a quality management system, and its processes, and also take steps to continually improve this system. It's no secret by now that ISO 9001 is big on a “process approach” to quality management, and Clause 4.4 (Quality Management System and its Processes) is basically saying that now that the organization has a firm understanding of their organizational context, and has determined the scope of its QMS, it must now develop the appropriate processes to support that system and ensure it performs effectively. So essentially, management must determine what processes are needed to meet organizational, customer, interested parties, and legal requirements in a continuous and efficient manner.

- In order to accomplish this effectively and meet the requirements of the ISO 9001:2015 standard, organizations must determine the inputs that are needed, and outputs that can be expected, as well as the sequence and interactions of applicable processes. The first step in meeting this requirement again goes back to the first 3 sections of clause 4 (Understanding the context of the organization), its internal and external issues, interested parties, and determining the scope of the QMS, which in turn provide inputs for the remaining processes needed to support the QMS, and ensure that the desired outputs will be produced.

- Many of the processes developed, if they have not already been implemented, will produce outputs, which then become inputs to various other processes. Understanding this relationship is essential to developing processes that interact sequentially or in conjunction with one another, without contradicting. Process mapping is an effective way to ensure that processes are set up in this way.
Organizations must determine and apply criteria and methods required to ensure the effective operation and control of those processes. What benchmark is to be used to ensure that processes are performing as expected? In order to monitor and measure the effectiveness of a process, or anything else for that matter, criteria must be established to measure against.

What resources are needed? And what is the availability of those resources to ensure processes are implemented effectively? What raw materials, supplies, or information will be required? And are they readily available to adequately implement the processes?

Responsibilities and authorities must be assigned for each particular process so that there is no question as to who is responsible for the implementation and communication of the process and its intended outcome.

It’s essential to ensure that the quality management systems and its processes are regularly evaluated for change and improvement opportunities, and that those changes and improvements are adequately implemented.

Along with change and improvements, processes must be evaluated for risk and opportunity to ensure that possible risks are adequately mitigated, and opportunities are identified and taken advantage of, for the benefit of organizational growth and improvement.

In addition, organizations are required to develop and retain documented information in order to support the operation of its process, and confirm that processes are being
implemented effectively. It’s up to the organization to determine the type and to what extent this documentation will be maintained. The goal here is to make sure that the process can be understood and carried out in an effective way by the people performing the work, and that there is a way to provide evidence of the desired result.

So, this concludes Chapter 4 on context of the organization, which outlines the importance of understanding the internal and external issues, as well as interested parties that have a direct effect on the organization, so that management can have a better understanding of the risks and opportunities that lie ahead, as well as provide context when determining the scope of the quality management system and its processes.
Gregory Peckford
CHAPTER 5

CLAUSE 5: LEADERSHIP

“One of the tests of leadership is the ability to recognize a problem before it becomes an emergency.”

-Arnold H. Glasow

In this chapter we will take a look at clause 5 (Leadership), which covers the requirements for top management to demonstrate leadership & commitment with respect to the quality management system, promote customer focus, establish clear roles and responsibilities, and a policy that reflects that commitment to quality and the satisfaction of its customers. It is imperative that top management commit and strive to continually improve the effectiveness of the QMS. Management must provide the appropriate guidance, necessary resources, and promote the importance of the quality management system and its processes through example and leadership. In the 2008 version of the standard, this section was titled Management Commitment, and although the commitment by management to support the quality management system is still important, ISO has taken this a step further in the new 2015 edition and now requires that management must take on greater involvement in a leadership role in the quality management function, and actively promote the culture of quality and the implementation of the QMS throughout the organization.
Also, for those who are familiar with the 2008 edition, ISO has removed the requirement for organizations to appoint a quality management representative and now requires that all manager and executives share the responsibility of quality in the organization, and must be active participants in the quality management function. That is not to say that the role of quality manager has been rendered obsolete, but just that management must share in the responsibility and awareness in regards to quality in the organization. Top management may still decide to delegate the role of managing the QMS and its processes, but the ultimate responsibility for ensuring its implementation and effectiveness remains with top management.

So now that we have a general understanding of the concept of leadership in regards to management's responsibility to the QMS, let's take closer looks at each of the sub-clauses within section 5 (Leadership) which are:

- 5.1. Leadership and commitment;
- 5.2. Policy;
- 5.3. Organizational roles, responsibilities and authorities;

5.1 Leadership and commitment

5.1.1 General
ISO 9001:2015 has reinforced the requirement for top management to take on more commitment and responsibility when it comes to the organization's quality management system.
Top management can no longer delegate this responsibility and forget about it. This has been an issue in the past. It’s common for an organization's top management to assign a quality manager to the role of managing every aspect of the QMS, and then divert their focus to other areas of the operation. This is no longer acceptable in the latest edition of the standard, as top management must demonstrate leadership and commitment with respect to the quality management system, by taking ownership and being accountable for the effectiveness of the organization's QMS, as well as supporting other relevant management roles to demonstrate leadership. All levels of management must be committed and involved in the implementation and improvement of an organization's QMS in order for the processes and procedures to be effective and encourage buy-in from all personnel. But the ultimate responsibility for ensuring its implementation and effectiveness remains with top management.

Top management must now ensure the development of a quality policy, and quality objectives, that are compatible with the context and strategic direction of the organization. We will discuss the requirements of the quality policy and objectives in more detail coming up, but it’s the responsibility of top management that the policy and objectives be established and adequately communicated to all personnel and interested parties.

Management must ensure the quality management system requirements have been adequately integrated into the organization's business processes. This is to say that the quality management system must be viewed as not just a stand-alone function to be handled by the quality department,
but as a business management tool to be utilized throughout the organization.

- Top management must make it a priority to promote the concepts of process approach, risk-based thinking, and improvement, in order to lead by example in the development and nurturing of a quality culture throughout the organization.

- Of course, management must ensure that adequate resources needed for the quality management system have been determined and are readily available.

- Leadership is about guiding the way, and top management must lead by example, and ensure everyone in the organization is on the same page in regards to the QMS and nurturing a quality culture. Communicating the importance and value placed on effective quality management and conforming to the requirements of the quality management system achieves this. This is a very important requirement, because if top management can show they are committed to the quality function, then the rest of the organization will be more inclined to follow suit.

- Ensuring that the quality management system is performing effectively and producing the results anticipated during the planning and implementation stages, top management must perform review and monitoring activities in order to adequately gauge how well the system is performing. The management review processes as well as gathering and deciphering key performance indicators are valuable tools that organizations should use for this purpose.
If an organization hopes to establish and implement an effective quality management system that truly adds value to both the organization itself, as well as its customers, top management must lead the charge in the encouragement and support of personnel to utilize the system and contribute to its effectiveness.

Top management are required to promote improvement of the quality management system and the organization as a whole. Establishing processes is just one step; personnel must know that they will have the support of top management to improve on those processes when applicable. This is important, as it’s easy to fall into the trap of continuing to perform activities that are not effective simply because it's the way things have always been done. Change and improvement are necessary, and top management must promote this view.

I mentioned earlier that top management involvement is important to getting buy-in from all personnel. One key element of this is getting all other management roles involved and on the same page with top management's vision. I’m referring to positions such as middle management or department managers. They must be supported and given the resources necessary to promote and encourage the effective application of the QMS in their individual areas, in order for the organization as a whole to ultimately reach its goals.

So as you can see, ISO 9001:2015 places a lot of value on the leadership and commitment of top management within an organization to champion the implementation and success of a functional quality management system.
5.1.2: Customer focus

Management must not only focus on the internal needs and responsibilities within its own organization, but also demonstrate leadership and commitment with respect to customer focus. This means that organizations must have a clear understanding of their customers’ needs and expectations, and ensure that the QMS and its processes are set up in such a way to continuously deliver on those needs.

- Top management must ensure that all customer, statutory and regulatory requirements have been determined, understood, and met on a consistent basis. It’s very important to make those determinations up-front, so that a clear understanding of the customer requirements is achieved and adequate attention and resources are assigned to those requirements.

- In addition to customer and legal requirements, risks and opportunities that may have an effect on conformity of products and services and the ability of the organization to enhance customer satisfaction must be determined and adequately addressed.

- Top management must also ensure that the organization remains focused on achieving and enhancing customer satisfaction. This is an ongoing activity that should continuously evolve.

We will discuss each of these requirements in much more detail later in the book, so I will just stress the importance that top management keep customer focus a constant priority. The requirement of sub-clause 5.1.2 (Customer Focus) will be adequately met with the implementation of various other requirements within the ISO 9001:2015 standard.
5.2: Policy (Quality Policy)

5.2.1: Establishing the quality policy

Organizations are required to develop, implement and maintain a clear quality policy that conveys internally and externally that the organization promotes a quality culture and aims to achieve customer satisfaction. The quality policy is the top-tier document for the QMS, and provides a high-level description of the organization's commitment to quality. To ensure that everyone has a clear comprehension of its purpose, and be on the same page with the organization's strategic direction, the policy should be written in clear, easy-to-understand language. Top management may delegate the development of the quality policy, but it is ultimately the responsibility of top management to provide input and vision to the contents of the policy. This is the organization's mission statement in terms of quality, and its commitment to improvement and customer satisfaction.

- Section 5.2.1 of the ISO 9001:2015 standard requires that the quality policy be appropriate to the context of the organization, and reinforce its purpose and strategic direction. This is a short, high-level glimpse at what the organization is all about, what they do well, and where they strive to be in the future. This goes back to clause 4.1 (understanding the organization and its context) but is obviously just a short glimpse into the information deriving from that process.

- The quality policy must also provide a framework for developing and implementing the organization's quality objectives. This is not the place to list or document the organization's objectives, however, it should reference that the organization shall establish such objectives, and strive to meet and continuously improve them. Of course the quality
objectives are going to relate to the organizational context and strategic direction reflected in the quality policy.

- The policy must reflect the organization's commitment to satisfy applicable requirements. This is pretty self-explanatory and should not be over-complicated when it comes to the quality policy. A simple statement showing the organization's commitment to meeting all applicable requirements is sufficient. It is not the place to explain what those requirements are, or how the organization plans to meet them – just that they are committed to do so.

- The organization's policy should also reflect a commitment to continually improve the established quality management system. Again this does not need to be over-complicated. No need to explain the methods used for continuous improvement efforts, simply that the organization will strive to improve its QMS, wherever and whenever possible.

5.2.2: Communicating the quality policy

It’s one thing to establish a quality policy that reflects the organization's commitment to the effective implementation of the QMS, but if nobody is aware of its existence or contents, then it is pretty much worthless. It is top management's responsibility to ensure that the policy is communicated so that everyone in the organization can align with the organization's direction and commitment to quality.

- Section 5.2.2 states that the quality policy must be maintained as documented information. This is not meant to be an idea passed around in a boardroom and never formally documented. It is meant to be a tangible and controlled document that can be shared, distributed, posted, referenced and revised when necessary.
The policy must be adequately communicated, understood, and applied by all areas and personnel within the organization to ensure everyone in the organization is aware and on the same page with management's commitment. Everyone within the organization should be aware of the policy, and how or where to find it. They do not need to recite it from memory if questioned, but a clear understanding of its general message is enough.

Clause 5.2.2 also requires that the quality policy be available to relevant interested parties outside of the organization's internal structure. This is a new requirement for ISO 9001:2015, but it's not difficult to implement. Many organizations may include the policy on their website or marketing material. It may also be included in the organization's quality manual, if they have this document (which ISO 9001:2015 no longer requires). They post it in worksite locations so that it is available to all personnel and interested parties that may have access to such areas. ISO 9001 does not stipulate how this should be accomplished, so it is up to the organization to determine how they wish to make this document available to their relevant interested parties.

5.3: Organizational roles, responsibilities and authorities

Now let's take a look at organizational roles, responsibilities and authorities in terms of the quality management system. Another required function of top management, according to clause 5.3 of the ISO 9001:2015 standard, is to ensure that responsibility and authority for all relevant roles has been clearly defined and communicated.
throughout the organization; that everyone understands his or her assigned responsibilities and authorities with respect to the quality management system. Making sure that roles and responsibilities have been clearly defined helps to streamline processes and reduce confusion. Everyone in the organization should have a clear understanding of what their specific responsibilities are, and where the boundaries of their respective authority begin and end. It’s also important that everyone in the organization have a clear picture of who to approach for guidance or resolution of issues pertaining to all other areas of the organization, in order to ensure that processes and the day-to-day operations run as smoothly as possible.

- Top management are required to assign the responsibilities and authorities to ensure that the quality management system conforms to the requirements of the ISO 9001:2015 standard. Now, as I mentioned in the opening to chapter 5, there is no longer a requirement for top management to appoint a management representative to oversee the implementation, and day-to-day operations of the quality management system, and in turn the oversight of this requirement to manage compliance to the ISO 9001 standard. However, that does not mean that organizations should no longer appoint such an individual to perform this task. It just means that top management have the discretion to manage this responsibility in the best means necessary for their specific organization.

- Organizations are required to assign the responsibilities and authorities to ensure that established processes are producing the intended results. There’s a monitoring and measurement component to this requirement. In other areas of the standard we see the requirements for review, monitoring, and measurement of processes to specified criteria, to ensure the process produces an intended result. Well, someone within the organization must be responsible for managing this
function for his or her respective processes. At a department level, this could be the department manager's responsibility, coupled with the quality department to perform audits and quality control activities. However this is performed, it must be clear who holds the responsibility and ownership for the success of each process.

- There must be assigned responsibilities for reporting to top management and others as applicable, on the performance of the quality management system, as well as any possible opportunities for improvement that may arise. Again, this could be assigned to a QMS management representative or quality manager, but it does not have to be – as long as it is clearly identified who will hold this responsibility of keeping top management informed of the health and efficiency of the organization's quality management system. The management review process is a valuable tool for this reporting of information, and it would be likely that this individual would be the one facilitating this review.

- There must be assigned responsibilities and authorities to ensure the promotion of customer focus, as well as awareness of organizational and client requirements throughout the organization. Of course this role will be different depending on the size and complexity of an organization. This can be a simple task to keep focus on in a small to medium-sized business; however, in large corporations it can be difficult to keep sight of this requirement. There may be a whole department in charge of just this requirement alone. But large or small, this is a vital activity for any organization, and should be managed as such.

- There must be assigned responsibilities and authorities to ensure that the integrity of the QMS has been maintained
whenever changes to the quality management system have been planned and implemented. This requirement will require a considerable amount of document control process, as well as process management. Again it is usually up to the QMS management representative to ensure this requirement is adhered to, but whoever is assigned this role must have an in-depth understanding of the organization's QMS and associated processes, as well as process interaction to ensure the effects of change are captured in all areas.

ISO does not state any documentation requirements for assigning roles, responsibilities and authorities; however, it’s advised that documentation be established so that there is no confusion as to who is responsible when it comes to the QMS. Also, this helps clearly define what responsibilities and authorities fall within a particular role. This could be accomplished with job description and organizational charts. Regardless of who within the organization has been assigned the roles pertaining to the quality management system, ISO 9001:2015 requires that all top management demonstrate leadership and commitment with respect to the quality management system.

Coming up we will discuss clause 6, which covers the requirements for planning with respect to the quality management system. In this section we will cover topics on actions to address risk and opportunity when planning for the QMS, establishing quality objectives, planning to achieve them once they have been defined, and planning for change to the quality management system.
CHAPTER 6

CLAUSE 6: PLANNING

“Time is the scarcest resource and unless it is managed nothing else can be managed.”

-Peter Drucker

In this chapter, we will discuss Clause 6 (Planning) as it applies to the organization's quality management system. This section is also where we see the addition of risk-based thinking become more prevalent in the ISO 9001:2015 standard. This is a very significant addition to the standard, as well as to the implementation of a quality management system. Organizations are required to plan and implement processes to address and manage risk, and also take advantage of current or foreseeable opportunities that may be beneficial to the organization. I really like that the new standard included the consideration of opportunity. The quality function in organizations generally focuses more on the negative aspects, whether it be looking for problems, or trying to prevent them in the first place. But quality management, if used effectively, can be a powerful tool for improvement and positive growth. Risk and opportunity are things that should be considered in all aspects of an organization's quality management system, but even more so in the planning stages.
Another important consideration for organizations in the planning stage is the effective management of change. It is vital for management to fully understand the reasons for implementing changes, as well as the possible consequences that those changes can have on the effectiveness of an organization’s quality management system. Change is unavoidable, and a necessity in order for organizations to grow and keep pace with industry and customer needs. But as is the case with risk, if it is not managed effectively and taken into consideration while performing planning activities, it can disrupt processes and cause negative effects on maintaining conformity to product and service requirements.

So let's take a look at the main topics that will be covered in this chapter on planning for the quality management system.

6.1 Actions required to address not only risk, but also possible opportunities.

6.2 Quality objectives and planning to achieve them

6.3 Planning of changes to the quality management system

6.1: Actions to address risks and opportunities

Clause 6.1 of the standard states that when planning for the quality management system, organizations must consider the issues and requirements referred to in sections 4.1 (understanding the organization) and 4.2 (understanding the needs and expectations of interested parties) and then determine the risk and opportunities that need to be addressed in order to:

- Ensure that the quality management system can effectively achieve the intended results that it was developed to achieve.
➢ Ensure that it must be capable of enhancing desirable effects.

➢ Prevent or reduce, undesirable effects; and

➢ Achieve improvement.

So, section 4 (determining the context of the organization) can be considered to be the first step in the risk management process. Planning for risk should be based on the information gathered while assessing internal and external issues, as well as the needs of interested parties that have an effect on the QMS. What foreseen risks or possible opportunities are present, both now or in the future, that must be mitigated or taken advantage of. It is important to consider and avoid, mitigate, or even accept risk, based on informed decisions that could have negative implications. But it is equally important to take advantage of positive opportunities that can lead to the adoption of new practices or product and service options, identifying new markets, or introducing new and improved technologies that can help to ensure long-term success for the organization, and improved customer satisfaction.

➢ Of course the next step organizations must take, once they have considered all of the issues and applicable interested parties, and identified the risks and opportunities associated with the quality management system, is how to take action or implement strategies based on this vital information.

➢ Organizations must plan actions to address risk and opportunities,

  ○ However, ISO allows the organization the discretion to develop their own methods for addressing risk, as long as they are adequately planned and integrated into its quality management system processes.
As well, organizations are required to evaluate the effectiveness of these actions once they have been implemented. Again, we have to stress the importance of evaluating what has been done, in order to be sure it has the planned effect, as well as take the opportunity to refine as needed. This is a good example of the plan-do-check-act cycle in action.

ISO does not require this process for identifying and managing risk to be documented, however, it would be a good practice to do so. This is an important function for the success of the organization and should be managed as such. Also, it would be difficult to show an auditor that the organization is following the requirement without this documentation as evidence of conformity.

6.2: Quality objectives and planning to achieve them

Section 6.2.1 of the ISO 9001:2015 standard deals with the requirement for organizations to establish quality objectives that are consistent with the organization's scope of business and quality commitment. These objectives must also be measurable and relevant to the established functions and levels within the organization in order to be effective. It's important to develop objectives that are realistically achievable, and not arbitrary words that look good on paper. This is far too often the case, and does not serve the organization or promote growth and improvement.

Quality Objectives must be consistent with the organization's quality policy, which is the master document that sets the tone for the quality management system, and the objectives must be aligned, and back up the themes contained within the policy.
Along with the quality policy, objectives must also reflect all applicable requirements,

They must also be relevant to conformity of products and services, and must help the organization achieve its goal of enhancing customer satisfaction.

As mentioned at the beginning of this section, quality objectives must be monitored and measurable in order to assess and confirm the effectiveness of the intended purpose, and result of the objective. This is a very important step, and a common thread throughout the ISO standard, to continually monitor and measure processes, procedures, and the QMS as a whole. It is also included as a required input to the management review process. Management are required to consider the extent to which quality objectives have been met.

And of course, all of this is useless, unless a clear method has been established of communicating these objectives, so that everyone within the organization has a clear understanding of their individual roles in achieving the established objectives – as well as sharing the organization's direction and commitment to the QMS, while achieving customer satisfaction,

And implementing applicable updates as needed.

(6.2.2) Once an organization has established its quality objectives, and has captured all of the requirements necessary to ensure they are relevant to their intended purpose and function, it is essential to plan how the organization will achieve them effectively. ISO 9001 requires that management assess at a minimum the following factors.
What will be done? What is the process, and actions required to complete the objective? Each action plan must be specific to the individual objective.

What resources are required to complete the objective, and are those resources available to the required parties performing the activities? Such resources might include people, time, facilities, or equipment, just to name a few.

Who will be responsible for the successful completion of the objective, as well as the monitoring and measuring of activities to ensure they are effective? This responsibility should be assigned and understood by all involved, and those people must be held accountable for those responsibilities.

What is the timeline for the completion of the objective? How much time is required? Each objective will be different, and require a particular amount of time to be reasonably accomplished based on the activities involved.

And how will the results of the completed objective be evaluated? How can management determine if the objective reached its goal effectively, and if it provided the intended result? Are the planned actions adequate to achieve the objective?

Not considering these factors or performing adequate planning while determining quality objectives and the methods for carrying them out, will usually result in objectives that stall over time, and become ineffective, or in most cases are never completed successfully.
6.3: Planning of changes

Section 6.3 of the standard outlines the importance of planning for changes to the quality management system. As I mentioned in the beginning of this chapter, change is unavoidable, and necessary for growth and improvement. But significant changes that are not planned for effectively can cause negative effects on the organization. Which is why ISO 9001:2015 has added this new section, requiring organizations to carry out needed changes in a planned manner, and an adequate change management process.

- In doing so, organizations must consider and understand the purpose of the changes, and their potential consequences once they have been implemented. Are the changes necessary, and do they add value to the QMS and improve on the system or its processes?

- What effect will this change have on other areas or functions of the QMS, or the integrity of the quality management system, and its ability to conform to requirements? What areas of the QMS are going to be affected by the change, and what actions are required to mitigate this?

- Are the required resources available to successfully implement these changes? Proactively planning for change and ensuring the resources are available can save a lot of time, effort and cost, as opposed to dealing with this in the moment.

- And have responsibilities and authorities been assigned, or re-allocated to the appropriate personnel to ensure that the changes are implemented and measured for effectiveness?
It is commonplace for organizations to make changes, but unless these factors are addressed beforehand, the possibility for undesirable consequences becomes far greater, and the process is no longer controlled.

Again, and I will keep bringing this up throughout this book, ISO 9001 does not require documented information such as procedures or records regarding change management, but it would be highly beneficial and advised to do so.

In the next chapter we will take a look at clause 7, and discuss the requirements for support of the quality management system, that organizations ensure that there are adequate resources available to support the QMS, that the personnel performing the work have the appropriate competencies to carry out the work effectively and are aware of the requirements of the QMS, and that communications relevant to the QMS are carried out effectively to all internal and external parties.
CHAPTER 7

CLAUSE 7: SUPPORT

“No employer today is independent of those about him. He cannot succeed alone, no matter how great his ability or capital. Business today is more than ever a question of cooperation.”

-Orison Swett Marden

With the planning stage complete, organizations must now ensure that adequate resources, infrastructure, informed and competent personnel, as well as communication and documentation structure have been established and are available to ensure successful planned execution of the organizational strategy. Obviously, all the best-laid plans are meaningless without the structure to implement and support them in action. In the previous version of the standard, this section was referred to as resource management, and only required organizations to consider the resources such as human resources, infrastructure, and work environment. However, the 2015 version requires that the organization consider all factors that help to support the organization and its quality management system, including monitoring and measuring of processes, and the less tangible, but no less important aspect of organizational knowledge, which is the knowledge generally gained by experience that is specific to the organization and used to achieve the organization's objectives. So take a more detailed look at each section of clause 7 for a better
understanding of the ISO 9001:2015 requirements for supporting the organization and its quality management system.

In this chapter we will discuss the following sub-clauses of section 7, Support, which are:

- 7.1 Resources;
- 7.2 Competence;
- 7.3 Awareness;
- 7.4 Communication; and
- 7.5 Documented information

7.1: Resources

7.1.1: General

For a quality management system to function effectively, management must ensure that the resources required for the implementation and improvement of that system have been determined and are available to the people that need it. This will require targeted budgeting and planning efforts relating to the QMS specifically, in order to address such functions as internal and external audit, training, human resources, infrastructure, and monitoring and measurement equipment, as well as for the maintenance of such equipment.

- Section 7.1.1, states that organizations must determine and assess, not only the capabilities, but also the limitations and constraints of the internal resources which are currently available, as well as what will need to be obtained from
external sources in order to meet the requirements and continuous improvement efforts of the QMS. Are there adequate facilities and appropriate working environments available? Has the correct equipment and tooling been acquired in order to perform the work efficiently and to the correct standards? Are there adequate numbers of personnel to perform the work, and are they competent for the responsibilities they have been assigned?

- If such resources are not currently available, then the organization must determine how to obtain these resources. Organizations may outsource certain functions, or tasks, associated with the QMS, which is completely acceptable, as long as this use of external providers has been adequately planned for and controlled.

7.1.2: People

Obviously, one of the key resources that must be determined and provided by the organization to ensure the effective implementation of the quality management system, and the operation and control of its processes, are trained, responsible, and competent personnel. Not everyone has the same interpretation of competency, but personnel involved in the implementation and oversight of the organization's quality management system and operational processes should be trained, knowledgeable, and experienced in their respective area. The organization must ensure that they are adequately staffed in this regard and that all personnel are on board with the strategic direction and culture of the organization.

7.1.3: Infrastructure

Along with competent personnel, organizations must determine and provide adequate infrastructure for the operation of its processes. This infrastructure will differ significantly between organizational types, and will be largely determined by the type of product or service
they provide. Some of the types of infrastructure required to achieve conformity of product and service are:

- **Buildings and utilities.** This can include office space, warehouse, or industrial facilities for manufacturing or storage.

- **Equipment,** including both hardware and software. What machinery, physical tooling, or software is needed to produce the organization's products and services and ensure quality is maintained? A manufacturing company would have heavy requirements for machinery and automation technologies, whereas an IT service provider would have a primary need for computer hardware and software capabilities. How about software for quality control and assurance tracking? This is not a requirement, but something to consider in an organization with a complex quality management system scope.

- **Transportation requirements** must also be considered for moving personnel, products, or materials. There could be major logistical and cost factors to consider in regards to an organization's transportation requirements.

- **And information and communication technology** such as computers, Internet and networks, phones and other sources of technology relevant to the organizational needs.

Not all of these requirements will be managed by the organization itself, but may be outsourced to other organizations that specialize in each specific area. A manufacturing organization may outsource their transportation requirements and have a delivery or trucking service take care of this function on their behalf. Either way, this vital infrastructure must be determined and made available.
7.1.4: Environment for the operation of processes

A suitable working environment relating to both the human factors and physical conditions for which work is performed must be taken into consideration and managed within the quality management system. This required work environment would vary significantly depending on the products and services produced by an organization. It’s essential for management to be sensitive to these factors, and continuously monitor and measure the conditions in which processes are being performed in order to maintain an appropriate working environment that is conducive to its scope of work.

Section 7.1.4 (Environment for the operation of processes) states that organizations must determine and maintain a suitable working environment needed to achieve conformity to product and services by considering a combination of human and physical factors such as:

- Social, in terms of providing a work environment that is calm and free from discriminatory or confrontational behaviour.

- Psychological, stress-free and reducing the effects of burnout and overwork.

- And physical factors for a comfortable work environment such as temperature, humidity, lighting, and noise just to name a few.

If the organization maintains an office environment, it is important to consider the comfort of its employees in regards to room temperature and lighting. In a manufacturing environment, there may be temperature requirements relating to the product itself, in which case calibrated temperature control instruments may be required. What health and safety requirements are there to be considered that are specific to its particular working environment?
7.1.5: Monitoring and measuring resources

7.1.5.1: General

Determining the requirements and equipment needed for monitoring and measuring activities is an extremely vital part of verifying the conformity of products and services to requirements. We’ll discuss in more detail later in the book regarding the determination of the requirements, criteria, and frequency of monitoring and measurement activities. However, in section 7.1.5, ISO states that organizations are required to ensure that the resources provided for this function are suitable for the type of monitoring and measuring activities being performed, and that they are properly maintained and fit for the purpose. So what exactly is required here?

- Basically, the organization must ensure that they have the appropriate monitoring and measurement resources on hand that are suitable for the work being performed. If they’re required to take weight measurements, then they must ensure they have scales that are capable of handling the size and type of product to be weighed, and that the scale can show the required increments. In the case of machining processes, does the organization possess the instruments to measure the required material thicknesses or tolerances? If temperature is a factor, does the organization possess the appropriate measuring devices capable of reading such temperatures to the precise increments required? This could be room temperature, product or component operating temperature or any other that applies.

- When considering fitness for purpose of these monitoring and measuring resources, the organization must ensure they have processes in place for maintaining these resources so that they can be relied upon to continuously provide the results necessary to meet requirements. What are the
maintenance and calibration schedules? What inspections will be required to give a level of confidence that the resource is performing as expected, or in other words, that it is fit for purpose.

ISO 9001 also requires that organizations retain applicable documented information as appropriate in order to show evidence of fitness for purpose of monitoring and measuring resources. This is important, not only to show compliance to the standard, but also to allow organizations to maintain a level of control and confidence in the monitoring and measurement processes.

7.1.5.2: Measurement traceability
Along with suitability and fitness for purpose, it’s important for organizations to determine measurement traceability requirements. This may be an organizational or customer requirement, or may be necessary to meet industry or regulatory standards. Whatever the reason, if measurement traceability is required, it's important for the organization to establish processes to manage this effectively. Measurement traceability provides confidence that the results of measurement activities are accurate and valid. Providing traceability for measurement activities and devices is not only to provide proof of compliance to the standard or customer and regulatory requirements, but also as a means of identifying previous measurement results that could be compromised should a faulty or inaccurate measuring device be inadvertently used. In this case, the organization will have a clear trail to identifying any affected product or process as a result of the use of unfit for purpose devices. As a matter of fact, it’s a requirement that organizations implement a process for identifying and taking appropriate actions when the validity of previous measuring results are in question.

Let's say Tom is measuring the thickness of a machine part that has a very low tolerance for deviation. In the process of performing
his measurement, he notices that the calibrated callipers he is using have been damaged at some point and not tagged or removed from service. Since there is no way of determining when this damage occurred it’s impossible to be certain that the same instrument has not been used on previously completed parts, allowing the possibility for error in measurements. Since the organization has a clear process for traceability, they can assess which parts have been measured using this exact tool back to its last calibration date and then take the necessary steps to rectify those suspect parts or products. Without this traceability process, there would be no way to determine what parts have been affected.

- So as I’ve mentioned, one of the most common ways of providing confidence in the validity of measurement results or devices is to have them calibrated, or verified, at specified intervals against applicable international, or national standards. If no such standards exist, the basis used for calibration, or verification, must be recorded. So for example, in the United States and Canada, the national standard for measures is the National Institute of Standards and Technology, or NIST for short. This is just one example, but if there is no available standard, then the manufacturer will likely provide this criterion for their specific device.

- But of course, just calibrating something doesn’t provide traceability – documenting and retaining records of this calibration, and when and where this calibrated device has been used, is essential for maintaining traceability of measurement activities. There must also be some process for identifying and determining calibration status. This can be as simple as attaching a calibration label to the measurement tool. This makes it easy to identify the calibration status of that tool at the time of use.
Once calibrated, monitoring and measuring equipment must be safeguarded from improper adjustments and protected from damage and deterioration that would invalidate the measurement result. So there must be processes for proper storage and care of measurement equipment. Depending on the type of equipment, there could be adjustment screws or mechanisms that can be restricted by the use of tamper proof labels, locking wires, or gels and wax coatings. Software must also be verified to meet the intended application prior to initial use and reconfirmed when used for monitoring and measurement purposes.

7.1.6: Organizational knowledge

Clause 7.1.6 identifies organizational knowledge as a resource that must be maintained and available, as necessary, for the operation of its processes and in achieving conformity of products and services. This is a new requirement in the ISO 9001:2015 standard, and it may be difficult for organizations to understand their responsibilities with respect to organizational knowledge. Every organization has amassed knowledge based on its collective experience that is specific to its scope of operation and the products and services they create. This knowledge can come from various sources such as past experience, and lessons learned through previous successes and failures. It’s important that management assess this knowledge and determine if it’s sufficient to meet its specific needs and requirements, and if additional information and knowledge is required through outside sources such as training and knowledge sharing. All changes and industry trends must be evaluated to ensure that organizational knowledge is updated as required to meet those changing requirements.

So basically, organizations must determine what knowledge is necessary to be successful in their specific scope of operation, and then assess the knowledge they already possess through combined
experience, intellectual property, and other sources at their disposal, as well as determine how they can obtain the necessary knowledge that they do not currently possess. This could be achieved through hiring personnel with the knowledge and experience required, training existing personnel, or many other methods that are necessary, on how this knowledge will be made available to those that need it most, and how changes to knowledge requirements will be addressed in order to ensure effective operation and production of products and services that conform to requirements.

7.2: Competence

Section 7.2 highlights the requirements for assessing personnel competency. Organizations must ensure that all personnel performing work at any level of the quality management system, that may have a direct or indirect effect on product quality and conformity to requirements, are competent in their ability to successfully and effectively achieve quality objectives.

- In order to ensure this, management must first determine what those required competencies are,

- And then ensure that personnel meet these predetermined competency requirements on the basis of appropriate education, training, skills, and experience.

- If gaps are identified, appropriate actions must be taken to reach the required competency through training, or any other steps that are deemed necessary, and perform evaluation to ensure the effectiveness of actions taken, or training provided.

- And also retain any appropriate documented information in order to demonstrate the required competency.
Similar to the requirements in section 7.1.6 (Organizational knowledge), organizations must determine what skills, training, and experience are necessary to ensure effective operation and production of products and services that conform to requirements. Once this level of competency has been determined, it is time to take stock and assess the level of competence that is already available within the organization and its personnel, and then identify any areas that will require additional resources to obtain such competency.

There are various ways in which an organization can ensure they have competent personnel performing work that affects the performance of the quality management system, such as training existing personnel, hiring personnel, or contracting out specific tasks to individuals, or other organizations with the required competency or skill set or simply implementing a mentoring process within the organization. ISO 9001 does not dictate how competency should be addressed, just that processes be implemented to control and manage it appropriately. Competent personnel will make all the difference to an organization's ability to achieve and maintain success. It's important though, not to confuse training for competency. Training is but one step in obtaining competency in a task or operation. It must be combined with a level of experience. It’s up to the organization to determine what their definition of competency is for their specific area, or scope of work. Of course there are also other considerations such as industry standards and professional certification requirements when it comes to competency of personnel.

7.3: Awareness

Section 7.3 discusses the requirements for awareness. This used to be covered under competency in the old 2008 version of the standard, but has now been separated to form its own section. And for good
reason! Because all of the planning and implementation of the organization's QMS that we have discussed so far, and will continue to cover in the coming chapters, would be pointless if the personnel performing the work under this system were not aware of the organization's commitment and direction, as well as their own individual responsibilities with regards to the quality management system. This awareness promotes alignment across the organization, and at all levels. It's important that personnel understand, and have an awareness of their individual roles with regards to the QMS, but it's also essential that they be aware of top management's commitment to establishing and implementing a quality management system that is functional and followed by everyone throughout the organization, top management included. Top management must lead by example and make everyone aware of the processes and requirements that have been put in place.

- One way to achieve this is by ensuring everyone is aware and understands the organization's quality policy. We discussed the quality policy back in chapter 5, The quality policy is the to-tier document for the QMS, and provides a high-level description of the organization's commitment to quality. It's not only required, but also essential to ensure that everyone is aware and has a clear comprehension of its purpose, and be on the same page with the organization's strategic direction. The policy should be written in clear, easy-to-understand language and distributed, posted, and made available to all personnel. Personnel are not required to know this policy word for word, but they should understand its message and key components.

- Personnel must also be aware of relevant quality objectives so that everyone within the organization has a clear understanding of their individual roles in achieving the established objectives. As well as sharing the organization's
direction, and commitment to the QMS, while achieving customer satisfaction, and implementing applicable updates as needed. Otherwise, how could management ever hope to fulfill those objectives and commitments to quality and customer satisfaction?

➢ When people are aware of just how their actions or contributions fit into the grand scheme of things, or how their individual efforts can help produce a positive outcome, they are much more likely to buy into a system or process. This is why it's essential that all personnel within the organization have an awareness of what their roles are with regards to the quality management system, and how they are contributing to the success of the organization by implementing and following the QMS processes and procedures. Sharing customer feedback and accolades is a great way to reinforce this message.

➢ On the flip side of this, it is also important that each individual understand the consequences, or implications of not conforming to the processes and procedures laid out in the QMS. Not all personnel will have an understanding of what effect skipping, or not following the system can have in areas that they are not directly involved in. So it's important to share this information and promote awareness of why the systems and processes have been put in place.

Put yourself in the role of a Quality Auditor for a moment, imagine you have just completed the documentation review portion of an audit and determined that the organization has all of the processes and procedures in place for a functional QMS. You then make observations of workers as they perform their tasks and notice they are not following the established processes you had just reviewed. Upon interviewing personnel, you get consistent feedback
that they are not aware of the established process. What would you determine as the root cause of this discrepancy? Is it the workers’ fault for not following a process or procedure that they have not been adequately made aware of? Or would you direct your attention to management and try to determine why the workers are not receiving the information that is vital to the success of their individual task and ultimately the success of the organization? Most people will follow the rules and guidelines set out for them, but if they are not made aware of these policies and guidelines, then they are being set up for failure from the start.

7.4: Communication

In the previous section we discussed the requirement for organizations to ensure that all personnel have an awareness of the QMS, the organization's commitment to quality, and the importance of their individual contributions when it comes to successful implementation of the quality management system. In order to facilitate this awareness, it’s essential to establish clear communication processes. Without effective communication there can be no expectation of personnel awareness. This may seem obvious, but communication within organizations, especially large corporations, can be difficult and sometimes overlooked and when not managed effectively can cause major issues and inefficiencies.

Clause 7.4 of the standard requires organizations to determine the internal and external communication strategies that are relevant to the quality management system, such as:

- What information will be communicated? Of course it’s impossible to nail down every piece of information that will be communicated in the operation of a business, and some information will carry more weight than others. It’s up to the organization to determine what information is important to
ensure effective operation of its system and processes both within the organization and externally. What information is required by its internal personnel in order to perform their work effectively? As well as, what must be shared with its clients and relevant interested parties?

- When does this information need to be communicated? What is the frequency of communication? Some information must be distributed at specific times in order to meet schedules. What are the frequencies of status reports? Are they weekly, monthly, daily? This is just one example, and this can only be determined within the scope and context of the organization.

- Who requires the information? Who is the organization communicating with, and are they receiving the correct information? Again, well-established roles and responsibilities within the organization will make this step much easier and efficient. Who is required to have specific information in order to do their jobs effectively? Also, when dealing with external bodies such as customers and suppliers, it's important to establish early on who will be the point of contact, or communication, for specific forms of information? Otherwise, this information may be misunderstood, misinterpreted, or completely lost.

- How will the information be communicated? Will verbal communication be sufficient? The problem with this is there is no record that the communication actually took place. Depending on the type of information being shared, there are many ways in which it may be communicated. It could be in the form of written reports, or letters, emails, or a combination of some, or all of these methods. If verbal is used, maybe it must be followed up with an email for records purposes. Also, it is important to get feedback on
communication to ensure that the parties receiving the information actually understand the intent of the communication.

- Who is responsible for communicating specific information? This must be determined as part of the roles and responsibilities within the organization, and can be further refined as needed. But I have to stress the importance of making this determination, and ensuring that everyone is aware of who is responsible for delivering pertinent information. This one step can make or break a communication strategy within an organization. If not managed correctly, it can cause confusion and have negative impacts on the organization's operation.

Again, communication is extremely difficult to formalize and capture in a process, but making determinations on the most important information that is relevant to the effective operation of the QMS can make this a much more manageable process.

7.5: Documented information

In this chapter we will discuss clause 7.5 (Documented Information) which highlights the requirements for creating and controlling documentation required to support the quality management system. The requirements for documentation and records control have changed significantly in the new version of the standard, and reflect the advances in technology and cover all forms of media for documenting data relevant to the quality management system. The requirements for maintaining hard copy manuals and procedures that were very prevalent in the previous versions of the standard are much less prescriptive. Much of how organizations manage and control documentation and records has been left up to the organization itself, based on their specific needs and requirements. What works for one
organization may not be sufficient, or necessary, for another to satisfy the requirements of its own QMS.

I think at this point it is important to clarify the new term “Documented Information” used in the ISO 9001:2015 standard. In the previous versions of the standard, ISO used the distinct terms “documents”, which is information used in the performance of tasks or operations such as procedures, policies, work instructions, and blank checklist. Documentation is used by an organization to aid in the efficiency of processes. This information requires revision controls to ensure the most up to date information is available. And “records”, which is historical information used as an evidence of a process, task, or procedure such as completed checklists, inspection, or audit reports, and so on. This information must be controlled, however, revision status is no longer required as it’s now a static snapshot in time. ISO 9001 has combined these terms to create “Documented Information” which includes any information that organizations need to operate, as well as information that they use to document the results that they achieve. So how do you know when ISO is referring to a document or a record? If the standard requires the organization to “retain” documented information, it means records. If the standard requires the organization to “maintain” documented information, then it means document. The terms retain and maintain are the telltale signs for what is required by the standard.

It’s also important to note that just because ISO 9001:2015 has adopted this new term when referring to both documents and records, there is no requirement for organizations to change their own system, or adopt this new term, documented information, itself. Just being aware of the meaning and requirements of the new term is sufficient.
7.5.1: General

So as I mentioned, ISO has become much less prescriptive when it comes to the requirements of maintaining and controlling documentation and has left this, for the most part, a decision of the organization, depending on what works best to meet the requirements of its QMS. However, there are specific areas within the standard where maintaining, or retention, of documented information is required.

- In order to meet this requirement, an organization's quality management system must include any documented information that is required by the ISO 9001 standard. So basically, whenever a clause of the standard states that documentation must be included, then this is not open to interpretation. The organization must maintain, or retain, this information. How this is documented is completely up to the organization.

- In addition to this, ISO also states that organizations must include documented information that has been determined by the organization to be necessary for the effectiveness of the quality management system. For example, there may be certain processes that an organization wish to ensure be carried out in a standardized and consistent manner, and therefore documenting this process would aid in this effort by providing a step-by-step instruction of the process and reduce the need for continuous training. Or there may be data that is to be recorded, that is relevant to the organization's scope of work.

Again this documented information can be in any form that works best for the organization, whether it is hard copy documentation, or electronically stored files. The extent of the information that must be documented is dependant of multiple
factors such as the size of the organization, type of activities, products and services, complexity of processes, and competency of personnel.

7.5.2: Creating and updating

ISO also lays out the requirements for creating and updating documented information required by the QMS in order to control and maintain the integrity of the information.

- When creating or updating documentation, regardless of the format used, organizations must ensure appropriate identification and description, such as, title, date, author of the document, or applicable reference numbers.

- The format, pertaining to language, software versions, or graphics, as well as media, such as hard copy, or electronic.

- The organization must also ensure review and approval processes are in place for documented information in order to verify suitability and adequacy of the information it contains.

7.5.3: Control of documented information

Along with the requirements for creating and updating, documented information must be adequately controlled to:

- Ensure it is available and suitable for use, as it is needed. Documented information is useless unless it is accessible to the people who need it most to complete their required tasks, whether that task is in the performance of a physical activity, or providing proof of conformity to standards.

- Documented information must also be adequately protected from such things as loss of confidentiality, improper use, or
loss of integrity. It’s important to make sure documented information is available to those that require it, but safeguarded from those who do not.

When developing methods of controlling documented information, organizations must consider and address many factors, such as:

- How the information will be distributed and accessed by those that need it? What are the retrieval methods, and how will the information be used? Is the information that is required by personnel located in an office or field setting? Is electronic access available, or will hard copies be required? How do these factors affect the control of the information?

- Storage and preservation must also be considered. Again hard paper copies or electronic media will require different forms of storage and preservation methods. If paper, how do you maintain legibility? Or inadvertent deletion if in the form of electronic data?

- Another important consideration would be control of changes such as revision control. Making sure that personnel have access to the latest and greatest revision of an applicable document, and inadvertent use of superseded documentation is properly safeguarded against.

- Finally, organizations must take into consideration retention and disposition of documented information. What requirements are there for the length of time documentation must be kept on file and accessible for proof of conformity, or audit purposes for example? And how will information be disposed of once it’s no longer required? Will it need to be
shredded, or somehow physically destroyed in the case of hard copies?

An organization must control not only its own documentation, but also all documented information coming from external origins that have relevance to the quality management system. This could be vendor documentation, or regulatory for example. How are they identified and distributed within the organization? So although the requirements for documentation and records control, now referred to as documented information in the new ISO 9001:2015 standard, have changed, it’s obvious that ISO still places strong value on the importance of organizations to consider its requirements for the management of this information regardless of the format it maintains.

ISO does not require that organizations develop documented procedures, or quality manuals, in order to meet the requirements of the standard. Or specify all records of conformity that must be maintained. However, organizations must make the determination as to what is required in order to maintain the integrity of its QMS, and conform to product and service requirements.
“Almost all quality improvement comes via simplification of design, manufacturing... layout, processes, and procedures.”
-Tom Peters

In this chapter we will take a look at the largest section of the ISO 9001 standard, clause 8 (Operations) which details the requirement for organizations to establish and control processes for determining and meeting the requirements of the products and services it provides. Up to this point the ISO 9001:2015 standard has been guiding us in the development of processes to support the organization's quality management system. In clause 8 (Operations), we are taking a closer look at the products and services themselves and the means to realize those products and services through each stage of the planning, design, production and final delivery or turnover process. We will discuss the importance of making informed determinations on the requirements for the products and services offered by the organization. Again, it does not matter if the organization is in the business of designing and manufacturing physical products, or providing services for a single client, or to the mass consumer, the organization must determine and implement processes that fit their own area of business and then ensure they follow those processes in order to achieve consistent results.
Let's take a closer look at the following sub-clauses of section 8 which are:

- 8.1. Operational planning and control;
- 8.2. Requirements for products and services;
- 8.3. Design and development of products and services;
- 8.4. Control of externally provided processes, products and services;
- 8.5. Production and service provisions;
- 8.6. Release of products and services; and
- 8.7. Control of nonconforming outputs.

8.1: Operational planning and control

Section 8.1 outlines the requirement for organizations to adequately plan, implement and control the production processes necessary to meet the requirements for their products and/or services, and also consider the actions determined while addressing such things as risk and change management as discussed in clause 6 (Planning). This relates back to clause 4.4 (Quality Management System and its processes), which is very similar in its requirement for organizations to determine and implement processes needed for the quality management system. The only difference here in 8.1 is that it’s focusing on those processes that are directly related to the products and services themselves. However, if the requirements of section 4.4 have been properly implemented, then most of the work has already been completed. Many organizations will likely have these processes
in place already, but they may need to be tweaked, formalized, and in some cases, documented in order to meet the requirements of the standard, show conformity to product or service requirements, and ensure consistent results.

- In order to meet the requirements of clause 8.1, organizations are required to determine the applicable requirements for the products and services they intend to offer their customers. This is pretty straightforward. What are the requirements that your product or service need to satisfy? What legal or client requirements have to be met? What functionality, shape, size, color or other design requirements does the product have to meet?

- Organizations must establish the criteria for evaluating the processes in order to:
  
  - Ensure they are performing as expected and producing the correct results.
  
  - Along with processes, products and services must be evaluated to established criteria to ensure that they meet the requirements established in the previous step, determining the requirements for products and services. This could be in the form of in-process, or final inspection activities, but whatever the method, the criterion for acceptance has to be predetermined.

- Organizations must determine the resources needed in order to support production and conform to the product and service requirements. What specific resources are needed to create the product or service and comply with requirements?
And they must also implement controls for the processes in accordance with the established criteria. What are the criteria? The criteria was established in the second bullet point of this section, now it is time to monitor and measure the processes against that criteria to make sure the processes meet the requirements. This can be done by in-process inspections or monitoring the output of the process.

Another requirement of clause 8.1 is maintaining and retaining documented information in order to:

- Provide confidence that the process has been carried out as planned;

- And to demonstrate that the product and service conforms to requirements. This could be in the form of inspection records or completed checklists for example.

There is no requirement in section 8.1 for organizations to document their operational processes and procedures, however, it would be very beneficial to do so, as to ensure consistency, reduce the effects of learning curves and make it easier to demonstrate conformity to the standard.

ISO 9001 states that the output of all this operational planning must be suitable to the organization’s own operations. So how does an organization show that it has performed the applicable planning that meets the requirements of clause 8.1 of the standard and that it is suitable to the organization's operations? By documenting such things as production procedures and processes, product or service specifications, work instructions, verification and inspection criteria, workflow charts, or policies, to name a few. These are all suggestions,
but every organization must determine what they wish to document based on what works best for their operation.

Section 8.1 also requires that the organization take steps to control planned changes. Review and understand the consequences of any unintended changes that may arise throughout the production process, as well as take necessary action to mitigate any adverse effects of those changes. Planning for and managing change is more thoroughly addressed in sections 6.3 and 8.5 of the standard (chapter 6 & again later in this chapter). For any number of reasons, organizations look to outside vendors, suppliers and service providers to perform some or many of the processes involved in the production of products and services. However, because a process is being performed by an outside source does not excuse the organization from its responsibility to control those outsource processes. This will be covered in more detail in clause 8.5 coming up later in this chapter.

8.2: Requirements for products and services

8.2.1: Customer communication

Section 8.2 outlines the responsibility of organizations to adequately manage requirements for products and services, and one of the most important ways to manage customer requirements relating to products and services is communication. Developing effective processes for communicating with the customer. Unfortunately, communicating effectively with customers is not always handled in a systematic way, which can have a negative impact on the success of an organization. Customer communication should be a planned process and implemented according. ISO 9001:2015 requires that organizations develop communication processes that address the following:
Provide product and service-related information such as accurate and up-to-date product data, pricing and related commercial considerations, service agreements, functionality and limitations, and so on.

Communication is also important in handling inquiries, contracts or orders. Customer inquiries can go both ways. The customer may require additional information that was not included in the product or service information package, or the organization may need clarification or additional information regarding requirements or other product or service related information. There should be clear and effective ways for handling this type of communication.

Communication processes for handling contract or order information, including changes, should be established. As is the case with inquiries, there should be clear processes in place to make communication on these important topics as smooth as possible for both parties.

Obtaining customer feedback relating to the product or service should be high on the list of information communicated and this includes complaints or grievances the customer may have. This is not always handled effectively by many organizations and nobody wants to hear negative feedback, but this information is vital to continuous improvement efforts and the ability to satisfy customer needs. It's up to the organization to determine what methods they will implement for obtaining feedback, but it should be easy for the customer to provide this information and include a process for investigation and action when necessary.

When applicable, organizations may be required to handle or possess customer property during operation or production of
a product or service, which could come in any manner of intellectual, physical or software based items. ISO 9001:2015 requires that organizations implement processes for communicating information specific to the handling and control of such items. Clause 8.5.3 (Property belonging to customers or external providers), later in this chapter, will discuss this in more detail.

- In the rare case where contingency actions are required, such as in high-risk operations, the standard requires that organizations establish communication processes for dealing with such an event. This would come into play in the planning stage to address the “what if” factor and ensuring that smooth and clear communication happens prior to and during contingency actions. This, of course, would have to be assessed by the organization based on the operation, if required at all.

Again ISO 9001:2015 does not require documented information for communication processes as it relates to products and services and has left it up to the discretion of the organization, but I would strongly encourage some manner of documentation.

8.2.2: Determining the requirements for products and services

Clause 8.2.2 requires that the organization develop processes to determine the requirements for products and services offered to its customers, and when doing so, they must define those requirements. So we already know that the organization must determine what the customer requirements are in order to satisfy the customer’s needs and expectations. You have to know what the customer wants in order to give it to them. But along with what the customer requires, there are other considerations that must be defined as well that the customer may not know about.
There are statutory and regulatory requirements that may apply to the product or service that must be factored in. There is a slight difference in the meaning of statutory and regulatory, but for the sake of this book we will refer to them as legal requirements. Organizations must establish processes for determining and defining these legal requirements and also staying up to date on any changes to those requirements. Some products or services will have vastly different legal requirements depending on the application or industry. Some products or services are highly regulated and some are not. It’s up to the organization to understand and be knowledgeable of all that apply.

Then there are the requirements that have been considered necessary by the organization itself. They have not been imposed by law, or by the customer, but through the knowledge and experience of the organization and what they deem necessary for the products and services they create. These requirements could also be driven by aesthetics or for branding purposes. The customer may or may not have any knowledge of these requirements, but they must be managed all the same.

Now that the processes are in place for determining and defining the requirements for its products and services, it must also determine if it is actually capable of realistically meeting those requirements and produce what it has claimed while conforming to the established requirements. This will come in the form of a review process, which we will look at in more detail in Clause 8.2.3 coming up next.

8.2.3: Review of the requirements of products and services

So as I mentioned previously, clause 8.2.3 takes us into more detail regarding the responsibility for organizations to review all relevant
requirements to ensure they are adequately understood and confirmed, and that the organization has the ability to meet those specified requirements prior to acceptance or formal commitment to supply products and services to the customer. This would of course be completed prior to finalizing the acceptance of a contract or order. The organization must review and ask themselves, do we truly understand all of the requirements associated with the particular product or service, and can we realistically meet those requirements in the agreed time frame. There are many additional factors to consider here that could affect this decision such as shipping requirements, scheduling conflicts, or outsource supplier capabilities, for example. So a systematic process for review is a must, however the complexity of this contract or order review process will be determined by the product or service being offered and the complexity of the requirements surrounding that product or service. As part of this review process, organizations are required to consider the following:

- All requirements as stated by the customer. We discussed how important it is for the organization to determine customer requirements and understand just what the customer’s needs are in terms of the product or service. Now it's a matter of reviewing those requirements and ensuring that the organization is capable of meeting the customer's needs and also commit to the delivery and post-delivery requirements that have been requested by the customer.

- Requirements that have not been stated by the customer but are necessary for the intended use of the product or service. These types of requirements may not be known by the customer but are essential for the success of the final product or service, and it is the responsibility of the organization to ensure these requirements are understood and factored into the review process accordingly.
As is the case with non-customer requirements, requirements specified by the organization itself will also have to be included in the review process. As mentioned earlier in this chapter, these organizational requirements could be driven by aesthetics or for branding purposes. The customer may or may not have any knowledge of these requirements but they must be considered all the same.

Depending on the product or service being offered, there will likely be statutory and regulatory, or legal requirements, which will have to be factored into the review process. Again, the complexity or extent of these requirements will be based on the product or service provided, but will be a major factor in the success of fulfilling a contractual obligation.

At times there may be contradicting contractual or order requirements that must be resolved prior to the organization committing to the supply of products or services to the customer. This could be due to many reasons such as specification revisions that take place between various stages of the contract or order process. Maybe there are conflicting requirements for delivery or completion dates between key players with the customer organization.

These issues must be addressed during the review process; otherwise the organization could be making a commitment without accurate data, which could affect its ability to meet requirements.

ISO also requires that organizations have a process for confirming the requirements of a contract or order in the case where the customer has provided no documented statement of requirements. This could be as simple as an email confirmation, confirming the agreed upon requirements. It’s up to the organization
to determine what works best for their business, but it should never be simply assumed that everyone involved is under the same understanding or agreement.

The ISO 9001:2015 standard requires that organizations retain documented information, or keep records, of the product and service review process in order to capture the results of the review and any new requirements that may have been introduced prior to, or during the review process. This could be a simple process such as stamping or signing the contract, or order form, or completing a standardized review checklist. This also makes it easy to show that the process is being performed as required by the standard.

8.2.4: Changes to requirements for products and services
When changes to requirements are identified during the process of product and service review, organizations are required to update all associated documentation such as specifications, contract or order documents, work orders and so on, to reflect those changes, and ensure that all relevant personnel are informed of the amendments.

8.3: Design and development of products and services

8.3.2: General
Section 8.3 of the ISO 9001:2015 standard outlines the responsibility of organizations to establish, implement and maintain a design and development process. Design and development activities necessary for products and services are required to be planned and controlled.

Design and development activities may or may not be applicable to an organization as this may not fall within the organization's scope of business. If an organization can justify that this function is not applicable, then obviously this requirement does not apply. However,
if the organization's scope of business does include design and development then a process must be developed to include the following considerations.

8.3.2: Design and development planning

By now, you may have noticed that planning is a major concept in the ISO 9001:2015 standard, and design and development is no different. Clause 8.3.2 requires that organizations determine the stages necessary for design and development. The purpose of this planning is to help in the management and control of the design process. This planning can be as simplified or complex as needed, depending on the product or service in question. If the organization is in the business of designing and manufacturing commercial or military aircraft or components, you can bet that the planning for design and development would be a massively involved and complex undertaking, as opposed to an organization designing paper cups for coffee retailers. Some degree of planning is required, but the process would look very different.

When planning for the stages and controls necessary for design and development, organizations are required to consider the following:

- The nature, duration and complexity of the design and development activities. This goes to what I just mentioned regarding the level of involvement needed for this process based on the complexity of the product or service being designed, and the length of time it will take to complete the required design process.

- What are the required stages for the design and development process? Organizations must determine the necessary tasks, or group of tasks, needed to complete the design and development process, as well as the sequence in which these
tasks should be performed. This also should include the review stage in order to identify gaps, or issues, and determine resolution.

- Verification and validation can sometimes cause confusion. Verification is the process of addressing conformance to requirements, or determining if design and development outputs align with the input requirements. While validation ensures that the design and development output is compatible with the intended use or application. Both verification and validation activities must be considered as part of the planning process.

- Responsibilities and authorities of the personnel involved in the design and development activities must also be considered in the planning stage. All personnel must be aware of, and understand their level of involvement and responsibility in the design and development process, as well as understand and accept the assigned authority.

- What resources will be required for the design and development of the organization's products and services? Will there be a need for facilities, equipment, supplies or software? How about personnel requirements?

- Clause 8.3.2 (Design and development planning) also requires that organizations consider interfaces between personnel involved in the design and development of products and services. How will people with responsibility and authority communicate and coordinate activities?

- Will there be any required involvement of customers, or end users, in the design and development stage? What would that
involvement look like? How would it be coordinated and managed efficiently?

- What are the requirements, if any, for subsequent provisions for the products and services? Are there shipping or storage requirements that have to be considered? How about packaging? These have to be factored in, and addressed, in the design and development process.

- If there are roles within the design and development of products and services that require involvement of customers, or other outside parties, the level of control that may lie with these parties must be considered. Maybe outsourced vendors, or subcontractors, have a certain degree of involvement in this process.

- And again, there is the requirement to consider what level, and type of documented information will be needed to show that the requirements have been met. And also, if there are to be documented procedures, flowcharts, or checklists to be developed in order to aid in the design and development process.

8.3.3: Design and development inputs

There are any number of inputs that could factor into the design and development of products and services, and they will vary greatly depending on the type of product or service being offered. And ISO 9001 states that all essential requirements must be determined. Clause 8.3.3 has included a list of five inputs that must be considered.

- Functional and performance requirements. I think this is pretty straightforward. Basically, the organization must determine how the product or service should function once it is in use, or handed over to the customer or end user. What
are the performance requirements and limitations? Let's take a cell phone as a quick example, what type of battery life will it have, what are the screen resolution requirements, Wi-Fi functionality, operating system, and so on.

- What similar design and development activities have been carried out in the past that the organization can collect valuable information and data from. This information and experience is extremely valuable and should be factored into the design and development process of the current product or service.

- Then there are the applicable statutory and regulatory requirements that have to be inputted into the design and development of products and services. Without factoring in the legal requirements, the organization could end up with a very expensive product that cannot be used as intended due to not meeting the laws that govern the use of such a product.

- Along with legal requirements, organizations may have standards and codes that also have to be input into the design and development process. Again this will depend heavily on the type of product or service offered, but some examples could be safety and environmental codes, or specific industry standards.

- And then there are the potential consequences of failure due to the nature of the product or service. What risks are involved in the operation, or use of the product or service, and what are the consequences of those risks? Are there safety or health concerns associated with a failure? Damage to other property? This must also be factored in as an input to the design and development process.
It is up to the organization to determine all of the required inputs to the design and development of its products and services, as long as they are complete, not open for interpretation, and adequate for the design and development purpose.

Inputs should be reviewed for conflict, and any such conflict must be resolved prior to implementing inputs into the design and development process.

And the organization must retain documented information, or records, pertaining to design and development inputs. Again, there is no requirement to develop documented processes, or procedures, for determining input requirements, but it would be very beneficial to do so – especially for organizations involved with complex design and development processes.

8.3.4: Design and development controls

Now that the requirements for developing, planning and input processes for design and development have been addressed, clause 8.3.4 states that the organization must implement controls to the design and development process. This is essentially a review process that also includes verification and validation activities. To ensure that the design and development activities are being carried out effectively, and achieving the desired result. Review, verification and validation may seem like similar activities, however, they are distinct processes that require a particular set of activities for each to be achieved effectively. Nonetheless, they can either be conducted as a combined effort or separately, depending on the complexity of the product or service being designed. Organizations must apply controls to ensure that:

- the results that are to be achieved have been adequately defined so there is a clear understanding of what the end goal
for the product and service should be. Obviously, you would not want to leave this to chance. You need to know exactly what your product will be before you begin producing it, or risk developing a product or service that does not perform or deliver as planned.

- Reviews must be conducted to ensure that the design and development result will meet the applicable requirements that have been determined in the planning stage of the process. Another purpose of the design and development review is to identify any problem areas, or gaps in the process that will need to be addressed. Reviews are not a ‘nice to have’, or an activity completed if time permits. If adequate review is not performed there could be major negative implications that will be costly to fix later in the production stages.

- In clause 8.3.2 (design and development planning) we discussed the requirement for organizations to plan for verification and validation activities for the design and development process. Well, now we are ensuring that those activities are being performed as planned. So to recap, design verification ensures that the design outputs meet the requirements of the design inputs, which we discussed in section 8.3.3 (design and development inputs). This can be done with inspection or testing activities.

- Validation is ensuring that the product does exactly what it is supposed to do. Did the design process produce the result it was meant to produce, and will it meet the requirements of its intended use, and under the appropriate design conditions.

- I mentioned earlier in this slide that one of the purposes of the review; verification and validation process is to identify problem areas and gaps in the design and development
process. Once these issues have been identified section 8.3.4 also requires that the organization take action to address those issues, and then review to ensure they are effective.

➢ And lastly, ISO 9001 requires that documented information of the control activities be retained, but again there is no mention of documenting the process or procedures for review, verification or validation activities. But this is something the organization will have to assess based on the scope and complexity of such activities.

8.3.5: Design and development outputs

Design and development outputs can come in any number of formats depending on the type of product or service being produced. Remember we are talking about the design and development stage in this section, so try not to confuse the output referred to here as the final product or completed service. An example of a design and development output could be an engineered drawing, or blueprint that will be used to manufacture a product, or component, an engineering work package, or installation instructions for a service to be performed.

➢ Of course there are countless other examples of outputs that could result from a design and development process, but regardless of the type, ISO 9001:2015 clause 8.3.5 (design and development outputs) requires that organizations ensure that, at a minimum, outputs meet input requirements, making sure that the output we get from the design process, encompasses or satisfies the requirements that had been previously determined to be essential in the creation of a successful product or service. We discussed the review, verification and validation process for providing confidence in this requirement, in the previous slide so we will not go into further detail here.
 Outputs must also be adequate for the subsequent processes relating to the product or service. Meaning outputs must provide information relating to supporting provisions for the product or service. This could reflect provisions for shipping requirements, packaging, logistics, or a host of many other areas that must be included in the design and development stage. The product is center stage of course, but the provisions surrounding and supporting the product must be factored into the design output requirements.

 Back in section 8.1 we discussed the requirement for organizations to establish criteria for the acceptance of products and services. This section requires that the output include, or make reference to these criteria. The output must contain information on exactly what the benchmarks are for the monitoring and measurement activities. What requirements, specifications, or tolerances must the product or service meet?

 The output of the design and development process must also clearly specify the characteristics of the product or service that may be essential for its safe and intended use. What exactly does this mean? Basically, the organizations must include any information that relates to how the product was designed to be used effectively and safely. Without this information the organization could be held liable should the product be used outside of its limitations or intended purpose or operation. How often do you see products with the warning label stating, “Please read the manufacturer's instructions manual, or safety precautions prior to use”?

 And again, ISO 9001 requires that documented information of the design and development outputs be retained.
8.3.6: Design and development changes

When changes are made during or after the design and development of products and services, it is imperative that these changes be properly identified, reviewed and controlled to ensure the product or service will continue to conform to established requirements, and that there are no adverse effects brought on by the change. Basically if a change is made, the organization must repeat the verification and validation processes. Section 8.3.6 requires that organizations retain documented information, or records, pertaining to any changes made. The records required by the standard are as follows:

- Design and development changes. This is pretty self-explanatory. Any changes identified must be recorded along with the supporting background information relevant to the change.

- As I mentioned at the start of this slide, changes require a review process to ensure the changes will conform to established requirements and the results of that review must be documented and retained.

- When design changes are identified and reviewed, they must then be authorized by individuals with the established authority to approve the incorporation of those changes into the original design. This authorization must be recorded and retained.

- Again when a design change has been identified, it must then undergo a review process to ensure the change will continue to conform to established requirements and that there are no adverse effects brought on by the change. If there are any adverse effects noted during the review process, actions must be taken to mitigate or prevent such impacts. Records of such actions must also be retained.
8.4: Control of externally provided processes, products and services

Clause 8.4 of the ISO 9001:2015 standard outlines the requirements for organizations to control the processes, products, or services that will be supplied by other parties outside of the organization. And that all externally provided processes, products, or services conform to established requirements. So basically, organizations must establish processes for procurement and purchasing activities, whether they be of raw material to be incorporated into the overall product or service they produce, or services sourced out to a subcontractor. It’s common for organizations to assume that the responsibility for controlling the processes related to a product or service supplied from an external supplier, or subcontractor, rests solely with that outsourced organization’s internal systems. And that once the order or contract is finalized they can wash their hands off it until they receive the final product or service they requested. This is a mistake that could have major cost, schedule and reputation implications and cause the organization to become noncompliant with their original requirements and responsibility to the customer.

Ultimately, it is the responsibility of the organization to ensure that the product or service they provide conform to established requirements. The customer does not care if the fault lies with one of the organizations suppliers or subcontractors, all they see is that the final product or service has fallen short of expectation.

8.4.1: General

Section 8.4.1, general, states that, at a minimum, organizations must determine the controls to be applied to the following:

- Products and services or raw materials supplied from external suppliers that are to be incorporated into the organization's
own product or service. For example, a cell phone manufacturer may produce a cellular handheld device to consumers under the banner of the organization, however, the manufacture and supply of various internal parts may be outsourced to other manufacturers that specialize in such components, such as transistors or display technology.

➢ In some cases, it may be required for an organization to have certain products or services provided, or drop shipped, directly to the customer. An example of this might be an electrical construction organization that has been contracted to construct a power station. Certain pre-assembled equipment like transformers or control stations, outsourced by others who specialize in the manufacture of such items may be delivered directly to the customer site. Even though others supply these items they still fall within the scope of the organization's original contract and must be controlled by the organization.

➢ It’s also common for organizations to look to outside sources for certain activities, or processes, that are either logistically, or cost effective, to be handled by a subcontracted organization that specializes in that particular activity. An example of this could be specialized testing, or inspection services, or transportation and delivery services. Maybe the organization is manufacturing a product and requires outsourcing for services they are not equipped to handle in house such as specialized painting or coating requirements.

All of the above mentioned requirements must be controlled in some manner by the organization.

Clause 8.4.1 (general) also requires that organizations determine the criteria for which external providers will be evaluated and
selected. Initial evaluation and selection of external providers could be based on any number of things such as capability and availability of the products or service required. Is the provider able to meet the requirements and the demand necessary? Is the cost of the product or service competitive and in line with the overall product or service strategy determined during the design process? How about the provider's quality management system? Is there a system in place and is it being adhered to?

Once the provider has been selected, it is equally important to develop criteria for monitoring the performance of the provider while the service is being performed. Again, this monitoring could be measured against an assortment of criteria, some carrying more weight than others. It is up to the organization to determine which criteria they wish to base their measurement on to ensure they are receiving the service that meets the requirements of their product or service. A couple of key performance indicators for this could be timeliness and accuracy of delivery. Are products arriving on time and in the correct quantities ordered? Is tracking of performance, or quality of the product being provided? Are there quality issues being noted, or items not performing as expected? What are the frequency or percentages of those issues?

If there are issues being noted based on the criteria the organization has been measuring against, regarding the performance of the external provider, then re-evaluation may be necessary such as performing audits of the provider's facility and QMS, or in service activities to try to determine if performance can be improved, or the selection of an alternate provider may be necessary.

ISO 9001:2015 also requires that the organization retain documented information relating to the monitoring, selection, evaluation and re-evaluation of its providers and any actions taken pertaining to the evaluations.
8.4.2: Type and extent of control
Clause 8.4.2 states that the organization must ensure that its ability to meet requirements and deliver conforming products and services to its customers is not adversely affected by its external providers. In order to meet this requirement, organizations must take the following steps:

- Ensure that the control of external provider process, products and service remain within the control of the organization's quality management system. Essentially, by following clause 8.4 of the standard, and setting up the procurement and purchasing processes within the QMS, in accordance with the guidelines of this standard, all you need do is make sure they are being followed and the organization will remain in compliance with this statement.

- Define the controls that the organization intends to apply to its external providers, as well as the resulting outputs of that external provider. Well, we basically covered this requirement in the last section, clause 8.4.1 when we discussed the organization's responsibility to determine the controls to be applied, as well as the criteria for evaluation of external providers. Now we just have to ensure they are being applied to both the external supplier, and the resulting output from that external supplier. How does the organization verify and validate that the output, whether that output be in the form of a drawing, document or physical product or service, conforms to requirements?

- Organizations must consider the impacts of external providers’ processes, if any, on its ability to meet statutory or regulatory requirements. Is there a legal requirement that could be affected by the use of an external provider and the
product and service they produce? And are adequate controls in place to ensure those requirements can be met?

➤ Organizations must also consider the effectiveness of the controls it has implemented for its external provider. Is the level of control sufficient to ensure the organization remains compliant with its customers and legal requirements as well as the requirements of its own QMS?

➤ And lastly, organizations are required to determine the verification activities needed to confirm that the externally provided processes, products and services conform to requirements. This could be as simple as conducting receiving inspection activities on the products that are delivered, or turned over to the organization from an external supplier. Checking correct quantities, confirming quality of the product or service, as well as the shipping and packaging requirements. These activities will of course be dependent on the type of product or service provided, but must be determined and planned for appropriately.

Controlling externally provided processes, products and services is vital to the success of the organization's own strategic objectives, and must be managed effectively. At the end of the day, the customer does not care that the substandard product or service provided to them is due to an externally provided component or sub service. All they see is that they have been presented with a product or service that does not conform to pre-established requirements, or meet their needs and expectations.

Let's say you purchase a cell phone that promises 14 hours of battery life under certain conditions, however the device shuts down by noon every day. Do you care that it's the faulty battery component supplied by an external supplier to the organization who
manufactures the phone? No, all you care about is the inconvenience, cost and time impact of being sold a product that does not meet your needs or deliver on its promise. How would it make you feel if on returning the defective device to the cell phone organization, you are informed that they are not responsible for the faulty battery, and that you will have to take it up with the manufacturer of that component. I’m willing to bet that your next cell phone purchase will be with an alternate organization. The organization is ultimately responsible for the control of all aspects, whether directly or indirectly, of the product or service they provide.

8.4.3: Information for external providers

Sub-clause 8.4.3 of the standard requires that organizations determine and confirm the adequacy of requirements prior to communicating those requirements to the external provider. Essentially, make sure you know what you need and then clearly communicate that to your external providers. If your provider does not have a clear understanding of the requirements and expectations of the organization, or are provided with inaccurate information regarding those requirements, then the likelihood of failure is greatly increased.

In order to ensure that the external provider has the information it needs to meet expectations, the organization must clearly communicate its requirements for:

- The processes, products and services to be provided.

- What approvals are required? As well as the methods, processes, and equipment for the development of those products and services? And what are the approvals required for the release of products and services? Who is required to give those approvals and what criteria are the approvals based on?
Organizations must adequately communicate the requirements for competency, and qualification of personnel. What training or certifications are required for certain activities? Is there a level of experience that is expected for personnel performing duties relating to the products and services being supplied to the organization? There may be legal or industry requirements to consider here.

What is the method of communication and interaction between the external provider and the organization? Who are the key contacts for each party? What is the preferred method of communication? Is it email, verbal, face-to-face meetings?

What control and performance monitoring requirements are expected? Will there be Key Performance Indicators that must be tracked and reported? Will there be site or facility visits required? Are their daily, weekly or monthly reporting requirements to be established?

What verification or validation activities are required to be conducted on the external provider's premises, work site or facility? This may be in the form of on-site audits performed by the organization directly, or by 3rd party sources on behalf of the organization. Many times the customer itself will want to perform these activities themselves.

All of this must be adequately communicated to the external provider to ensure that it is understood and accepted.

8.5: Product and service provisions

The first 3 sub-clauses of section 8 of the ISO 9001:2015 standard, deal primarily with the provisions for planning and design of products and services. In the last 3 sub clauses of section 8, we will
discuss provisions for the actual production and delivery of the organization's products and services. In section 8.5 of the standard (production and service provisions), we will look at the controls needed for production and service, identification and traceability, control of property not belonging to the organization, preservation requirements, post-delivery, and change control.

8.5.1: Control of production and service provisions

The focus of sub-clause 8.5.1 is on the control of production and service provisions. Organizations are required to implement processes for production and services under controlled conditions. In order to achieve this effectively, there are a number of controlled conditions that must be considered, such as documented information pertaining to the products, services or activities to be produced or provided, as well as the results to be achieved.

- As we discussed in section 8.2 of the standard, organizations must determine and review all applicable requirements and characteristics related to the products and services they offer. So this information has already been determined. What 8.5.1 requires is that this information be documented and made readily available during the production phase in order to ensure that the final product or service will incorporate those established characteristics and requirements.

- In section 7.1.5 we discussed the requirement for organizations to determine and provide resources for monitoring and measurement of products and services for conformity to requirements. This is reiterated here as part of the controlled conditions for production of products and services.

- Along with the availability of monitoring and measuring resources, the organization must ensure that monitoring and
measurement activities are controlled and carried out at the appropriate stages in order to confirm that the acceptance criteria for products and services has been met. The criteria and methods for monitoring and measurement have already been established during the implementation of other areas of the standard, such as 8.1 (operational planning and control). It’s now time to implement this planning.

➢ Again we reference back to earlier sections of the standard such as section 7.1 (resources), in which the organization must determine and provide adequate infrastructure such as equipment, buildings, office space, storage, as well as the environment essential to efficient operations. This may seem obvious, but it’s vital to maintaining controlled conditions for the production of products and services.

➢ As is the case with monitoring and measurement, and infrastructure, the requirement for organizations to appoint competent people with the required qualifications has also been covered in far more detail in section 7 of the standard, however it is also included as one of the controlled conditions in the production stage. And again, this is a pretty obvious requirement. If you do not have the appropriately trained and competent personnel performing the work, the likelihood of consistently producing a quality product or service are very slim.

➢ There may be times, or specific circumstances, where a process output, product or service cannot be verified by measurement activities before it has been passed on to the customer or end user. This is a rare occurrence, but one that must be controlled. In such case, organizations must develop processes for validating its ability to achieve the intended result, and that the product or service will be fit for purpose.
Keep in mind that verification and validation are not the same thing, and will involve different processes or activities. Verification can be viewed as checking a product or service against predetermined specifications, however validation can be seen as ensuring that those specifications meet the needs of the end user. So you can see how the validation process becomes extremely important when verification is not possible.

- Human error will always be a factor in any type of business, so it is important for organizations to put processes in place to control and help eliminate, or reduce the effects of human error in its production and service provisions. This is where tools such as checklists, flowcharts and forms come into play. No matter how familiar a person may be with a particular task, there is always the chance that errors can occur. In fact, complacency is one of the main causes of human error. Following a checklist can eliminate this by providing the operator with a step-by-step guide so that critical steps are not overlooked or completed out of sequence. Control guards, or emergency shut offs, and templates are some other examples of safeguarding processes for human error. It’s up to the organization to determine which methods are best-suited for their type of operation.

- The last controlled condition with regards to production and service provisions is the implementation of product and service release, delivery and post-delivery activities. At what point is a product or service deemed ready for release to the end user, and on what criteria is that release based? How will the product or service be delivered, and what controls are needed to ensure the deliver process is efficient? And what activities are required once the product or service has been
delivered to the end user? What type of follow-up, technical assistance, and warranty processes will be put in place?

8.5.2: Identification and traceability

Section 8.5.2, deals with the requirements for organizations to develop processes for the Identification and traceability of products and services, or process outputs. Identification and traceability are two separate, but closely related concepts. Of course it would be impossible to maintain traceability without having some form of identification.

Organizations are required to use suitable means to identify outputs whenever it is necessary to ensure conformity of products and services. Well it’s safe to say that in most cases some form of identification for products will be necessary whether it be with part number and serial number, barcodes etched or affixed to the product, or with a document traveller, or work package of some kind. This is entirely up to the organization and will be based on the type of product and related requirements.

We have already discussed the importance of establishing requirements and criteria for which products and services will be monitored and measured against in order to ensure conformity. In this section ISO requires that the organization establish processes for identifying the status of those monitoring and measurement activities. Has the product met the established requirements, and does it conform to applicable criteria? Is the status of product clear to everyone? Again this can be easily achieved by maintaining records of the measurement results in the form of travelers, checklists, inspection reports or simple approval stamp, or signature from approved personnel.

Of course one of the most important reasons for identification of products and services is for traceability purposes. ISO does not
outright require that organizations provide traceability of its products and services, but states that when traceability is required, organizations must control identification of its products and services and maintain documented information in order to allow traceability. Now, why would an organization require traceability of its products and services? Well the customer, or regulatory bodies could require it, or by the organization itself depending on the type of product and service it produces. Traceability does not only apply to the completed product or service itself, but also to the component parts that go into the final makeup of that product or service. We discussed earlier about the importance of maintaining traceability of monitoring and measuring devices in order to enable identification of affected products should there be question regarding the conformity of that product. Well, how could you identify which products have been affected if you do not have clear identification and traceability of that product.

There also needs to be sufficient information recorded in order to ensure this process is effective, such as part numbers, serial numbers, date of manufacture, and so on. Maybe a simple dated batch number system would be sufficient for the type of product and service offered by the organization. I think the most common example would be in the situation of consumer product recalls. Without a well-managed process for traceability, this sort of activity would be virtually impossible.

8.5.3: Property belonging to customers and external providers
ISO 9001:2015 also requires that organizations develop processes to address property belonging to customers and external providers. Section 8.5.3 lays out these requirements.

Customer, or external provider property could come in many forms and not necessarily only physical property. Some examples of
customer, or external provider property, that may fall under the control of an organization are:

- Tooling and equipment,
- Templates and moulds,
- Shipping containers,
- Raw materials,
- Software and data,
- Or intellectual property.

In the case of performing services, the property could include access to customer of provider facilities, or work sites. There are many other types of property that could apply here, but this should give you a good starting point of what the standard is referring to.

So now that we understand what customer or external provider property is, let's take a look at the organization's responsibility to exercise care when this externally provided property is under their control.

The organization must identify externally provided property so that it is clear to everyone who this property belongs to. Identification methods established in section 8.5.2 can be used to help control this process. Externally provided property must be verified to ensure the status of the property. What condition is it in at the time it was provided? Is it adequate to meet the requirements for which it is intended? If it is to be incorporated into the final product, does it meet the established criteria? You would perform receiving inspection processes and documentation control with externally provided property the same as you would with any material received. Once externally provided property has been received, the organization must establish processes for protecting and safeguarding this property while under the control of the organization. How will the property be stored? What special conditions are required for such
property? In the case of data or software, how will it be safeguarded from unauthorized use or distribution?

In the event that externally provided property is damaged, lost, or otherwise unsuitable for use, there must be processes in place for reporting this to the customer, or provider, and maintaining clear documentation regarding the specifics of the current status of this property.

8.5.4: Preservation
Organizations are expected to develop adequate processes in order to protect and preserve product during the production phases. In order to break the preservation process down into more manageable chunks, it is helpful to determine the preservation requirements for each stage of the production process.

- Identification is a very important part of the preservation process. Product must be clearly identified throughout the production process in order to maintain control.

- Processes for handling product during production must be established to ensure adequate methods are used to protect the product from damage during physical handling. This could be for movement within the production phases, handling for storage, or transportation and shipping handling.

- Determining the correct packaging suited for the type of product is vital for preservation. This must be based on the product characteristics itself, shipping requirements, transportation methods, and storage. It’s up to the organization to determine what type of packaging will be required to protect the product to its final destination.
• Preservation during storage must be determined. Storing product prior to shipping is very common for organizations, and it is the responsibility of the organization to implement processes for adequate preservation of that product while being stored. This is more than just making sure there is adequate space to store the product, but also considering the environment necessary to preserve that product while being stored – considering things such as temperature, humidity and security just to name a few.

8.5.5: Post-delivery activities

The organization’s responsibility for their product or service does not end once the product has shipped, or the service has been turned over to the customer. Organizations are responsible to meet certain requirements for post-delivery activities that may include such things as warranty coverage, maintenance services, or other supplementary services agreed to as part of the contractual obligations.

    Post-delivery activities are extremely important to ongoing customer relationships and satisfaction. According to sub-clause 8.5.5 of the standard, some of the factors to consider when developing post-delivery activities are as follows:

    ➢ Post-delivery activities mandated by statutory and regulatory requirements. This could be in terms of recycling, or final disposal requirements that the regulatory body has mandated to remain the responsibility of the manufacturer of that product. This is common in environmentally sensitive products; such as tires for example.

    ➢ What are the possible undesirable consequences that the product or service could present if utilized incorrectly? This could be a strong consideration for medical drug
manufacturers for example. Products that could cause unsafe conditions to the public, or consumer, or damage to property.

- What is the nature, or use of that product? What is the lifecycle expectancy of the product or service? What reasonable amount of time could the end user expect to receive follow-up, or service assistance for the product or service?

- What are the customer requirements that have been stipulated and agreed to in the contract? What service provisions and warranty guarantees have been included? The organization must be certain it has the capability to meet these requirements before entering into an agreement.

- And customer feedback should be a high priority for all organizations. Both positive and negative feedback on the product or service they provide is vital to ensuring they are continuously improving, and are providing products and services that meet the requirements and expectations of its customers. Without this feedback, it would be very difficult for an organization to maintain long-term customer relationships.

8.5.6: Control of changes

We discussed back in chapter 6 about the importance of managing and controlling change that may have an effect on the organization's quality management system. In section 8.5.6, ISO 9001:2015 discusses control of changes as it applies to the production of products and services themselves.

Organizations are required to review and control any changes with regards to production and services. So this simply means that when changes are made, the resulting effect of those changes must be reviewed to ensure that conformity to requirements has been
maintained and that the change had the desired effect. Controls must be put in place to manage the effect of changes to other areas, or requirements, relating to that product or service.

In order to ensure there is adequate control of changes to production and service activities, ISO 9001:2015 requires that documented information be retained. Records documenting the review process and results, the persons authorizing the change, and all necessary actions resulting from the change review process. What follow up must be carried out, or what actions must be taken going forward, to mitigate the effects of such changes?

8.6: Release of products and services

I think it goes without saying that before handing over a product or service to a customer you would want to have some level of confidence that the product or service meets the requirements and expectations of your customers. In other words, it will perform the way you promised it would. If it doesn't, then you are likely going to spend valuable time, money and energy trying to meet that predetermined expectation after the fact, likely in an uncontrolled environment. This does not only inconvenience you as an organization but your customers as well, which will inevitably lead to soured relationships and no chance of renewed business. Obviously not the best business model! So you are going to want to ensure that the product or service you are supplying is conforming to requirements and customer expectations before it ever leaves the control of your organization. Where discrepancies can be rectified in an efficient and cost effective manner, and not affect the all-important customer relationships that are essential to a successful business for the long term. This is the intent behind section 8.6 of the ISO 9001:2015 standard.
Organizations are required to implement the verification and validation activities that have been previously planned in order to verify that products and services conform to requirements. This includes all stages of monitoring and measurement activities that take place at various intervals throughout the production life cycle of a particular product or service, as well as the final verification prior to release to the customer.

So you have determined the necessary verification activities that must be performed in order to provide confidence of conformity, now make sure they are completed before the product or service is released. It’s that simple. ISO takes this a little further and states that no release of products or services shall take place unless all of the verification activities have been completed to the satisfaction of the predetermined requirements. If for some reason this verification cannot be completed prior to release then there needs to be approval from someone within the organization, or customer if applicable, with the authority to approve such a concession.

As is generally the case, it would be pretty difficult to show that a product or service has been verified, and is in conformance with requirements without documented evidence of this verification. ISO 9001 states that documented information, or records, of release activities must be maintained. This is likely to be in the form of test results, inspection records, completed checklists and so on. These records should have all the pertinent information relating to the verification activities leading up to the release. This documented information not only provides evidence of conformity, but also traceability to the individual that authorized the release of a product or service. This allows for accountability for the process and a method of follow-up should it be necessary.
8.7: Control of nonconforming output

Section 8.7 of the ISO 9001:2015 standard discusses the requirements for control of nonconforming outputs. Nonconforming outputs are essentially the products and services produced by an organization that do not meet or conform to the established requirements. Such products may be faulty, damaged, or just not up to the level of quality considered acceptable by the organization, or its customers.

It’s very important for organizations to establish processes for controlling nonconforming product so that the effects of such products can be minimized, or corrected, and that they do not affect the conformity of other products or services, get delivered, or used unintentionally. This process should also not be limited to nonconforming products or services identified before delivery, but include actions necessary to address post-delivery nonconforming product as well.

You may think that if a nonconforming product is found then just correct it and move on, but this may not always be the most effective solution. There are additional options for dealing with nonconforming products that can be considered depending on the type and complexity of the non-conformance identified.

- If it is feasible to do so, the organization may choose to correct the non-conformance. If it were something that may be easily rectified prior to allowing, or releasing this product into service then of course this would be the most desirable option. If the non-conformance was not identified during verification activities prior to release, and the product or service is now in the possession of the customer, it may still be possible to correct the non-conformance either on the customer's premises, or by having the product returned.
If a nonconforming product has been identified and correction of the non-conformance is not an option, then the product must be identified as nonconforming and segregated from other products so that it does not become inadvertently used or delivered. This type of product would generally be contained in some manner and suspended from use or service. Many organizations will have special storage areas for such product that is clearly identified to allow for adequate segregation from other conforming product.

If the non-conformance was not identified during verification activities prior to release and the product or service is now in the possession of the customer, it is important to ensure that the customer is notified so that they may remove this product from service and discontinue use until a rectification action can take place. This could be a simple replacement of the product, on-site repair, or in some cases a recall may be necessary and have the item returned to the manufacturer. Whatever the method of rectification, the customer must be notified as soon as the non-conformance has been identified.

In some cases, a concession may be granted for nonconforming products or services. It may be possible that the product or service may still perform some, or all of its intended function yet a non-conformance still exists. Basically we know a non-conformance exists, but we are ok with using it anyway as is. Of course any concession would have to be authorized by the appropriate personnel, both within the organization itself, and most importantly, by the customer. It's important to note as well that all authorization for concessions must be documented to show that it was in fact authorized by personnel with the authority to do so.
It’s also important to note that any corrections made to rectify a nonconforming product, or service, must be subject to the same verification processes that have been put in place for the production of that product or service. In other words, it’s not acceptable to just fix the problem and just assume it is now in conformance with requirements. This conformance must be verified.

ISO 9001:2015 also requires organizations to retain documented information relating to nonconforming product or service. This documentation is vital to maintaining control of such nonconforming products and services. ISO lays out the information that must be included in such records.

- The nonconformity must be described so that there is a clear understanding of exactly what the nonconformity is. Most organizations will have developed a form for recording this information. This description should be simple and easy to understand.

- Description of all actions taken to correct, or mitigate the effects of the nonconformity must also be recorded so that everyone concerned can clearly see what actions have been taken.

- As we discussed earlier in this chapter, it's necessary to record any concessions that have been authorized regarding the nonconformance, and what the details are surrounding such concessions.

- And the records must include the identification of the authorized personnel who make the final decisions regarding actions taken in relation to the nonconformity.
So that concludes clause 8 (Operations), which details the requirement for organizations to establish and control processes for determining and meeting the requirements of the products and services it provides. This is a large section with a lot of information and requirements for an organization to implement, but the truth is, most of the requirements laid out in clause 8, and the standard as a whole in fact, are likely already in practice in some form or another, otherwise, an organization would never complete a single task or release a single product or service. The ISO 9001:2015 standard just encourages organizations to standardize those processes, refine them as necessary, and follow them consistently.
CHAPTER 9

CLAUSE 9: PERFORMANCE EVALUATION

“Profit in business comes from repeat customers, customers that boast about your project or service, and that bring friends with them.”

-W. Edwards Deming

In this chapter we will discuss clause 9 of the standard, which lays out the requirements for performance evaluation. In this section, organizations are required to evaluate the performance of the processes and systems that have been put in place in order to meet their strategic goals and conform to product or service requirements. This is not a requirement for an annual employee performance evaluation, this is looking at the complete quality management system, by analyzing data, performing audits and management review and determining the health and effectiveness of the system they have put in place, identifying gaps or deficiencies which can then be improved upon. This is a very important function for organizations to achieve optimal performance, but is sadly overlooked by many. It relies on management commitment and support to be truly effective. When managed and implemented effectively, performance evaluation
can be and extremely valuable tool for business improvement and success.

In this chapter we will discuss the following sub-clauses of section 9, (Performance Evaluation), which are:

- 9.1. Monitoring, measurement, analysis and evaluation;
- 9.2. Internal audit; and

9.1: Monitoring, measurement, analysis and evaluation

We have discussed earlier in the book about the requirements for organizations to monitor and measure processes relating to the production and final acceptance of products and services, specifically in chapter 8. In section 9.1 we will talk about the requirements for organizations to monitor and measure its quality management system and associated processes for suitability. As well as the requirements for performing analysis based on that outcome of the monitoring and measurement activities in order to accurately evaluate the performance of the QMS. This is essential to producing products and services that continuously conform to established requirements, and ultimately ensure that the organization meet and exceed customer expectation.

This is not the first time that we have encountered these requirements in the standard. For example, section 4.4.1 (Quality management system and its processes) states that the organization must determine and apply the criteria and methods, including monitoring, measurement, and related performance indicators,
needed to ensure the effective operation and control of processes necessary for the quality management system.

Also, in section 6.2, organizations must establish quality objectives that are measurable and monitored. This might seem like a relatively common sense requirement that once a system or process has been put in place that it be evaluated for effectiveness, and that it is producing the intended result. But unfortunately this is a very common gap in many organizations. Too often organizations will develop processes or implement a QMS with the best intentions, only to allow that process to go unchecked, or unchallenged until problems surface. Even then it’s common to fix the immediate issue and not revise its processes in order to address the root cause.

9.1.1: General
When determining its specific requirements for monitoring, measurement, analysis and evaluation, organizations must first determine:

- exactly what is it that needs to be monitored and measured. What internal processes and procedures must be evaluated? How about external processes that may have an effect on the organization's QMS? It would be difficult to come up with a single process that does not need some form of monitoring and evaluation. It will be dependent on the organization to determine just what those processes are, and what level of monitoring and evaluation will be necessary.

- What method of monitoring, measurement, analysis and evaluation will be required? What type of measurement and evaluation will be necessary? What type of data must be collected and how will that data be evaluated?
When will the monitoring and measurement activities be performed and at what frequency? What stage of the process or production cycle will require monitoring and measurement activities?

When will the results of monitoring and measurement activities be analyzed and evaluated? Is this going to happen in real time along with the monitoring and measurement activities, or will the results from those activities be gathered and analyzed at a separate time? What happens with this collected data? When will the results from the analysis stage be evaluated?

All of this information derived from monitoring, measurement, analysis and evaluation should be used to evaluate the performance and effectiveness of the organization's quality management system. When the data shows that corrections or adjustments are required, it is vital that the organization take actions to implement these changes.

Clause 9.1 also requires that the results of monitoring and measurement activities be retained as evidence.

9.1.2: Customer satisfaction

Customer satisfaction measures how products or services supplied by an organization meet or surpass a customer’s expectation. This is a very short section of the ISO 9001:2015 standard, but don't let the small amount of content included in clause 9.1.2 (Customer satisfaction) reflect the level of importance that organizations should place on this topic. The standard states that organizations shall monitor customer perception to the degree in which their needs and expectations have been fulfilled. The main thing to consider here is the word “perception”. Because perception can be very complex, and based on a multitude of factors that may be very difficult to measure. It’s important for organizations to develop processes for
capturing information relating to customer perception, and turning that information into useable data to provide organizations with a metric that they can use to manage and improve their business. In a competitive marketplace where businesses compete for customers, customer satisfaction is viewed as a key differentiator. Businesses who succeed in these cutthroat environments are the ones that make customer satisfaction a key element of their business strategy.

Picture two businesses that offer the exact same product. What will make you choose one over the other? If you had been given a favourable recommendation for one of those businesses, would that sway your opinion? Probably. So how does that recommendation originally start? More than likely it’s on the back of a good customer experience. Organizations who offer amazing customer experiences create environments where satisfaction is high, and customer advocates are plenty. This is an example of where customer satisfaction goes full circle. Not only can customer satisfaction help you keep a finger on the pulse of your existing customers, it can also act as a point of differentiation for new customers.

By measuring and tracking customer satisfaction you can put new processes in place to increase the overall quality of your customer service. Customer satisfaction plays an important role within any organization. Not only is it a leading indicator to measure customer loyalty, identify unhappy customers, and increase revenue; it is also a key point of differentiation that helps an organization to attract new customers in competitive business environments.

ISO 9001:2015 requires that organizations determine the methods used to capture and review customer perception. Some of the methods that an organization may adopt can include;

- Customer Surveys, which can consist of forms sent to the customer for completion, or in person surveys. Surveys
should also be done at predetermined periods so that the results can be evaluated for trends. For example, a survey could be conducted at the beginning of a project, or product delivery, and again later in the process allowing for comparison of results.

- Customer feedback on delivered products and services. This is very important data to collect and analyze in order to gauge the performance of an organization as seen through the eyes of the customer. Customer feedback can provide all sorts of insights into what customers want from a business. What is working well, and what they would like to see improved.

- Meetings with the customer. Open two-way communication is very important in obtaining a true understanding of the customer’s overall perception of the organization. Getting customer feedback directly from the customer first-hand is priceless data that can be actioned upon immediately, as well as allowing the organization to provide assurances of meeting requirements and expectations.

- Some additional examples of methods of gauging customer perception are gathering market share analysis, customer compliments and complaints, warranty claims, and dealer reports. Of course there are many other ways to acquire this extremely useful and important information from customers, and it is up to the organization to determine what will work best for their scope of business and customer relationships. This will look very different for an organization providing products or services to other organizations, as opposed to providing products and services to the general public or mass consumer.
9.1.3: Analysis and evaluation
We have discussed multiple times throughout this book about the importance for organizations to perform monitoring and measurement activities throughout all stages of the production of products and services, and the implementation of its quality management system. However, all of this monitoring and measurement would hold little value without adequate analysis and evaluation of the monitoring and measurement results and collected data. But before we get into the section requirements, let's just take a look at the key differences between performing analysis and evaluation activities.

*Analysis* is an objective, detailed and methodical examination of the data collected from monitoring and measurement results. It’s a process of breaking down the information in order to study and perform comparisons based on selected samples. This could be in the form of statistical quantitative data, or less formal qualitative analysis techniques. Data analysis aids the organization in sound decision making. *Evaluation* is achieved by making determinations or judgments based on the information gathered during analysis. Does the product or service meet the specified requirements? Does it perform as expected, or meet customer expectations? Does the process provide the desired outputs, and is the quality management system performing effectively? What is working and what will require adjustment?

So now that we have a clear understanding of what the distinct differences are in these two terms, let's take a look at what the ISO 9001:2015 standard actually requires. As I mentioned, Section 9.1.3 outlines the requirements for organizations to perform analysis and evaluation of appropriate data, and information arising from monitoring and measurement activities. The results of the examination and analysis must be used in order to evaluate key aspects of the organization's operations, such as:
Conformity of products and services. Again this seems pretty straightforward. You are naturally going to want to gather and analyze information and important data relating to the products and services in order to identify trends, or areas that could use some extra attention. What is the failure rate on manufactured products? What could be the root cause of the failures, or discrepancies? What can be done to reduce this rate? Are services meeting the requirements of the customer? What can be improved upon in this regard? This information should be collected, recorded, studied and evaluated to not only identify discrepancies, but also effective processes that can be leveraged in other areas. There are any number of ways to collect this data depending on the type of information gathered. It could be presented with charts or graphs. Whatever works best for the organization? There is no requirement for how this must be done.

Organizations must evaluate the degree of customer satisfaction. What type of data is being captured from the customer, and how is it being analyzed by the organization? Are customer surveys being performed? What is the feedback saying? What areas are in need of attention, and what is working well? What is the overall customer perception? How is this information and feedback being used to drive continuous improvement? How is the organization relaying its improvement measures back to the customer? Again customer surveys are one tool for collecting this information. Meetings, comments, complaints, and post-service follow-up are some other ways to understand the level of customer satisfaction. Again this should be documented for easy reference and tracking.
Organizations must analyze and evaluate the performance and effectiveness of its quality management system. This is extremely important to the success of an organization's QMS. It's not practical to think that once a system has been implemented, and processes developed, that everything would run smoothly without any further refinement. There are any number of ways that this can be achieved, but one of the most effective methods of analyzing and evaluating the QMS is through the internal audit process. We will discuss this in greater detail in the next section. Other valuable information could be the results of corrective actions taken against past non-conformances. Has the planned action been effective? Has it addressed the root cause of the problem? What lessons have been learned from the process, and how can they be shared and implemented in other areas of the QMS?

Planning is another area that must be considered and evaluated for effectiveness. We have discussed in length all through the ISO 9001:2015 standard about the importance of planning in regards to the organization's QMS, and operations and production of its products and services. Has this planning been effective? Has it produced the desired results? What could have been planned better with the knowledge and data gathered to date? How about planned changes? Has the planning been sufficient to meet the organization's objectives?

Have the actions taken to address risk and opportunities been effective? Have the risks been adequately mitigated? Have opportunities been taken advantage of, and captured to drive continuous improvement? What can the organization do better going forward in order to address risks and opportunities?
How about the performance of external providers? Has data been collected in order to properly analyze and evaluate the performance of the outside suppliers and service providers? Let's keep in mind that the standard requires that the organization maintain control of the processes performed by external providers that may have an effect on the QMS, or its ability to conform to product and service requirements. Keeping track of trends, on time performance, and deficiencies, as well as performing supplier audits, is a great way to evaluate the performance of external providers.

Lastly, and I think this is more of a recap, or culmination of what we have already covered previously in this section, is the evaluation of the need for improvements to the organization's quality management system. What has the analysis shown? What areas require extra attention and what lessons have been learned? What trends have been identified? And what actions will be taken to improve the system and its processes in order to benefit the organization and its customers? This step will be reinforced later in this section when we discuss the requirements for management review where a lot of this evaluation will take place.

9.2: Internal Audit

Like so many of the sections, which make up the ISO 9001:2015 standard, this next section covers a topic that warrants its own book (everything in due time). Internal Audit is such a vital part of maintaining a functional and effective quality management system. And although we could go into great detail on the many intricate facets of the internal audit process, we will stick to the specific requirements as stated by the ISO 9001 standard for purposes of this book.
According to ISO 9000:2015, the Fundamentals and Vocabulary standard, an audit is: “A systematic, independent, and documented process, for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.” In other words, making sure that what is happening in practice aligns with policies, processes and procedures. Audits should be carried out to look for areas for improvement and best practice. They should not be adversarial, or confrontational. Internal audits should be formal, planned, and organized. They are conducted in an impartial and objective manner following an agreed scope and procedure. Audits are used to gather facts and determine the degree to which requirements are being met.

As well as meeting the conformity requirements of ISO 9001, there is a lot of value to be added to an organization by making use of internal audits to gather other valuable information during the audit process. So much can be learned about the overall performance of an organization by simply communicating with people on other issues and ideas. The key is not to simply limit internal audits to conformity issues alone. There is a standard for Management Systems Auditing within the ISO 9001 family - ISO 19011. Organizations contemplating or conducting audits should obtain this invaluable standard.

Section 9.2 of the standard states that organizations must conduct internal audits at planned intervals. What does the standard mean by “planned intervals”? You will notice that there is no actual timeline given. That is because ISO 9001 does not dictate how often an organization is required to audit its own QMS. It is up to the organization to determine how often they will conduct internal audits on its own processes. It is, however, commonly accepted that those intervals be within a 6-month to annual interval, and in fact, if an organization is registered to the ISO 9001 standard, the certifying
Gregory Peckford

registrar, or certification authority will require a minimum of yearly internal audits as part of its certification acceptance criteria.

In order to manage this requirement, organizations can implement an audit schedule, outlining the planned audit intervals, including proposed dates and departments, or processes to be audited. The purpose of an internal audit programme, or schedule, is to plan the type, and number of audits, as well as to identify and provide the necessary resources to conduct them. It’s also important to note that it is not required to do a complete system audit in one shot! It's perfectly acceptable for the organization to segment, or break up the audit process, and plan for particular processes to be audited at specified times, which can be outlined in the audit schedule. Doing this alleviates some of the resources needed as well as time and disruptions to regular activities.

The whole point of the internal audit process is to provide information on whether the quality management system conforms to the organization's own requirements for its quality management system. And that it also conforms to the requirements of the ISO 9001:2015 standard.

- Now for the sake of maintaining certification to the ISO 9001 standard, and benefiting from the valuable concepts and frameworks it provides, it's vital that the organization perform internal audits to ensure it is in conformance of the requirements laid out in the standard. This is pretty straightforward, and required as part of the certification process.

- But most importantly, the organization must ensure that it is conforming to the requirements that it has set out for itself. These are the requirements that the organization has painstakingly established in order to produce the products
and services it offers its customers, and is how it maintains a level of customer satisfaction. This is by far the most important set of requirements to maintain conformity to. Without this, the organization does not stand a chance of being successful.

- Along with management review, internal audit of the organization's quality management system is an essential process for providing confidence in the effective implementation and maintenance of the QMS. Internal audits provide the organization with insights into the adequacy of its processes and documentation, conformance to requirements, how well they are operating, and where improvements are needed most. Is the organization following in practice what they have implemented in process, or procedures? Are objectives being achieved? Is there a satisfactory level of customer satisfaction? Are there ongoing efforts to identify continuous improvement opportunities, and are actions being taken to realize these opportunities?

So now that we know why we must perform internal audits, section 9.2.2 of the standard discusses exactly what must be done in order to accomplish this effectively. The section states that organizations must:

- Plan, establish, implement and maintain an audit program. This program must include the frequency of audits, how often and at what intervals will audits be performed? What methods, or how will the audits be conducted? Who is responsible for the audit program? What requirements must be considered while planning for the audit program? And how will the results of internal audits be reported?
You will notice that the standard does not state that documented information is maintained, or in other words that procedures be written for the audit program. Again this is left to the discretion of the organization. However, it would be extremely difficult, if not impossible, to maintain an effective audit program that truly adds value, and drives continuous improvement efforts, without having a documented process for this extremely important function.

When developing the audit program, or more accurately in this regard, the audit schedule, the organization must also take into consideration such factors as the importance of the processes being audited. Some processes carry more weight than others simply because they can have a greater effect on the success of the organization, or conformity of products and services to requirements. That's not to say that you only look at these processes and forget about all others. It's just that the frequency of audits will likely be greater for some processes than others, depending on the importance of those processes to the organization's overall operation.

Another consideration when determining the audit program, are changes that may have an effect on the organization. Whenever there is an aspect of the organization's operation that changes frequently, or has undergone a major change, it's important to capture this in the audit program to make sure that the changes are not only effective, but have not had a negative impact on the process being changed, as well as on other constituent processes. Have the effects of changes been adequately controlled, and have there been any unforeseen circumstances that must be addressed?
And of course, one of the major considerations, which must factor into the audit program, and unfortunately is often overlooked, are the results from previous audits. This does not have to be limited to internal audits performed by the organization, but also audits performed by outside parties such as customers and certification audits. If an area has been shown to have deficiencies in past, you will likely want to audit this area a little more frequently than other areas that have been performing well with no findings. The organization will also do well to schedule follow up audits for areas that have had issues in past audits to ensure that corrective actions have been implemented effectively.

Along with what we have already discussed in this chapter so far, there are other factors besides the frequency and audit scheduling that must be considered when planning and conducting an internal audit.

- A key consideration is of course the audit criteria, and scope of each audit. What exactly are you auditing against, and what are the boundaries of the audit? Audit criteria according to ISO 19011, Guidelines for Auditing Management Systems, are a set of policies, procedures, or requirements used as a reference, against which, audit evidence is compared. So obviously we have to know exactly what policies, procedures, and requirements are applicable to the scope of that audit. The audit scope generally includes the physical locations, organizational units, activities, and processes, as well as the time period covered in the audit. Both the audit criteria, and scope would typically be defined within the audit plan, developed, and distributed prior to commencing the audit activities, so that everyone involved is aware and on the same page with the process and what their individual roles are.
Selecting and assigning auditors to conduct the actual audit is a very important consideration. It's important to note that any individual within the organization can perform audits as long as they have been adequately trained on the process. Internal audits do not have to be performed by ISO certified auditors. What’s most important is that the auditor possesses the competence needed to achieve the audit objectives, and that a level of impartiality and objectivity are maintained. This of course means that you would not assign an individual to audit his or her own department, or that is known to have a close personal relationship, or conflict with the auditee. The findings must be based on facts and observations, and backed up with impartial evidence. Having multiple personnel within various departments, or work functions, trained and competent in the audit process available when necessary would be a good way for the organization to meet this requirement.

The audit process is meaningless unless the results of the audit are communicated, or reported to the relevant management personnel who can take the necessary steps to improve the system and the organization's operations as a whole. It is vital, and now a requirement of ISO 9001:2015, that management be aware and play a leading role in the health of the QMS. Results from the audit processes provide the best indication of how well the system is performing, and what areas need additional attention. In fact, audit reports are one of the necessary inputs required in the management review process, which we will discuss in detail coming up. Departmental managers must be aware of the audit results so that any findings that arise in their particular areas can be dealt with directly and effectively.
Another requirement of the organization with respect to its audit process is to ensure that appropriate correction, and corrective actions are taken in a timely manner. When non-conformances are noted during the audit process, there must be adequate corrective actions taken in order to fix the immediate issue, as well as address the root cause in order to prevent it from reoccurring. ISO states that corrective actions must be carried out without undue delay. This does not give a specific timeline for corrective action. This is because all corrective actions are different, and some will require more time to complete than others depending on the complexity of the issue, and the steps required to correct it. If the corrective action is relatively simple to complete, then it should be done as soon as practicable after the audit report has been released. If it requires an ongoing process for effective corrective action, an action plan should be developed to show the progress and steps being taken that will lead to the eventual correction of the issue.

And the last requirement to be considered is the retention of documented information as evidence of the implementation of the audit program and audit results. Remember, retention means “records”. What has been done? What has been identified both positive and negative, during the audit process? Remember, audit reports and results are a key input to the management review process, so it is essential that adequate records be kept for review. Plus, it is extremely important that records of corrective action be kept so that assessments can be made as to the effectiveness of those actions, as well as show evidence that corrective actions have been identified and implemented should the issue reoccur in future audits. One of the main areas an auditor should look for when performing an internal audit is the results from previous audits and the actions taken to correct
nonconformities. Without adequate record keeping this would be impossible to manage.

9.3: Management review

9.3.1: General

Many people have the impression that ISO 9001 requires organizations to gather all of its top management and quality personnel in a boardroom once a year to conduct a formal management review meeting. But in fact ISO does not state that the management review be a formal meeting at all, or that it be held once a year. The truth is, management review should be a continuous, ongoing process, if management is truly engaged with the organization's quality management system, as it should be, and are in fact required to be, with the latest 2015 standard.

The ISO 9001:2015 standard states that top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness, and alignment with the strategic direction of the organization. This could be monthly, quarterly, or yearly, depending on the organization, and the data being analyzed. Of course more frequent review is better. Performance metrics should be monitored with varying frequencies, some daily, some weekly, and some monthly; management cannot wait for six months to act on this information. If they do, it will be too late. The intent is to gauge the health of the quality management system and to drive continuous improvement throughout the organization. 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 be planned to ensure that the necessary information is collected ahead of time, allowing management to effectively carry out this evaluation.
9.3.2: Management review inputs

Of course, the organization would determine what additional inputs are important to determine the effectiveness of its own QMS, and operations. However, the ISO 9001:2015 standard provides the minimum inputs that must be considered during the management review process. These inputs include:

- The status from action from previous management reviews. It's important to review the action items and decisions made during previous reviews in order to determine if the actions have been implemented, and if they have been effective. It's a good idea to keep an action items log for management review meetings, or any business meeting for that matter, in order to keep track of these items, and ensure they are carried out as discussed. This is also a great way to gauge the effectiveness of the management review process itself.

- What changes have taken place within the internal structure of the organization, as well as externally, that may have an effect on the quality management system. This is important in order to make plans for dealing with such changes and ensuring that the QMS remains effective. A strategy implemented 6 months ago may no longer be effective once change has been introduced to the equation. It's important to bring those changes to the table during the review process. You may remember this from section 4.1 (Understanding the organization and its context) where management are required to monitor and review information about internal and external issues such as economics, technology, competition, values, and culture, just to name a few.

- An essential input to the management review process is the adequacy of resources previously assigned to the quality management system and its processes. Are the resources
sufficient? Are additional resources required? This can change very easily and must be addressed in order to maintain an effective QMS.

➢ In section 6.1, we discussed the importance of determining risks and opportunities that have an effect on the organization's quality management system. The management review is an opportune time to assess the effectiveness of actions taken to address risk and opportunities. Have the actions taken adequately reduced, or mitigated the risk? Have opportunities been taken advantage of? What additional actions may be required?

➢ One of the main goals of the management review, and top priorities for the management team involved, should be finding opportunities for improvement. It's important that everyone participates in this review and provides suggestions and ideas for improving the effectiveness of the QMS, and the organization as a whole. Bringing forward suggestions from personnel not present in the review is important for department managers, being the voice of the personnel performing the work on a daily basis who have unique knowledge of how to improve the processes they are involved in.

➢ The last input required by the ISO 9001:2015 standard to be considered during the management review process is actually a collection of data showing trends, and not a single piece of information. It’s information on the performance and effectiveness of the quality management system such as:

➢ Results from customer satisfaction monitoring and feedback. As we discussed in section 9.1.2 of the standard, this information can be gathered through the use of customer
surveys, complaints, warranty claims, or any number of methods. Whatever the method for collecting this data, it is important to include it in the management review process.

- The extent to which quality objectives have been met. You will remember back in section 6.2 of the standard, the organization is required to establish quality objectives that are measured, monitored, and updated as required. Well, the management review process is the ideal place for evaluating these objectives and determining if they are being met, and that they remain relevant and consistent with the organization's QMS and strategic direction.

- Process performance and conformity of products and services. These are two separate inputs actually, but it's important to review how well established processes are performing. Are they producing the results expected? Are they efficient, or can they be improved? This again will require input from personnel involved in the daily activities that make up these processes. Are products and services conforming to requirements? What are the results from inspections and customer feedback? What is the failure rate of products, or the success of services?

- A review of nonconformities and corrective actions. What trends are apparent when analyzing this data? Are corrective actions sufficient to fix the issue? Is there evidence of recurrence of issues? A tell tail sign that the organization is not getting to the true root cause of the problem. Are corrective actions being closed in a timely manner? If not, what is causing the delay, and what steps are required to remedy this?
Management must also review trends deriving from the results of monitoring and measurement activities. I mentioned during the lesson on section 9.1 that analysis and evaluation of monitoring and measurement results would be an important input to the management review process.

Again we talked about audit results earlier in this chapter, and the vital information that the audit process produces. This information is essential for management to get a clear picture of the performance and effectiveness of the quality management system. No management review would be complete without analysis of audit results. You will remember in section 9.2 (Internal Audit), which states that the organization shall ensure that the results of the audit are reported to management.

And lastly, but certainly not least important, however, many times overlooked, is the performance of external providers such as suppliers and subcontractors. Remember, the organization is responsible for processes performed by external providers that have an effect on the organization's QMS, and conformity of products and services. For this reason, it’s important to include this information in the management review process so that top management can gauge the performance of those external providers and make sound decisions regarding future relationships with those providers.

9.3.3: Management review outputs

Now of course, with all the inputs to be considered during the management review process, there is obviously going to be some clear outputs that result from all this review, analysis and evaluation. Section 9.3.3 of the ISO 9001:2015 standard requires that the
organization, at a minimum, make decisions and take action on outputs relating to the following:

- **Opportunities for improvement.** Now you might be thinking… “wait a minute, this was included as an input during that last section, how could it also be an output?” During the input stage of the review process we are looking for input from managers and personnel, based on their working knowledge of the organization's processes, and areas that they feel could be improved. Now it is up to management to decide on what actions, if any, will be taken to implement those improvements.

- **Need for change to the quality management system.** Using all of the inputs from the previous section will enable management to make informed evaluations and decisions on what may need to be changed in order to make the system more effective. What is not working and requires adjustment? What changes are necessary to improve the performance of the QMS, and ultimately the satisfaction of the customer?

- And the last output required from the management review process is **resources needed to support the quality management system.** Again, this was also an input, but the difference here is management must now determine what additional resources are required to support any opportunities for improvement, or changes that they have made the decision to implement.

So as you can see, the management review process is vitally important to the success and performance of the organization's quality management system. There is a lot of value to be gained by implementing a management review process so that it does not get overlooked. For this reason, among others, ISO requires that organizations retain documented information as evidence of the
results of management review. What has been reviewed? Who was involved? What decisions have been made? And who has been given responsibility for actions to be taken? This will help the organization manage the review process, and follow up activities, aid in future reviews, and also provide proof that the organization is fulfilling this requirement.

In the next chapter, we will take a detailed look at clause 10 (Improvement), which is the last section in the ISO 9001:2015 standard. This is a short section in content but a very important one in practice. Organizations are required to act on the analysis and evaluation activities conducted as part of the performance evaluation process in order to continually improve the quality management system and in turn enhance customer satisfaction.
CHAPTER 10

CLAUSE 10: IMPROVEMENT

“An organization's ability to learn, and translate that learning into action rapidly, is the ultimate competitive advantage. “

-Jack Welch

In this chapter we will discuss the final section in the ISO 9001:2015 standard, clause 10 (Improvement). Clause 10 is one of the shorter sections of the standard and as is the case with the performance evaluation processes discussed in clause 9, improvement is something that not all organizations recognize as a tangible process or management function and so it’s often times overlook. But it is vital for organizations to take advantage of lessons learned during normal operation and continually examine processes to discover and eliminate problems, as well as identify areas of improvement, challenging the status quo, and not getting trapped in the mindset of “this is how it's always been done!” Organizations must always look for new and improved methods for conducting business and delivering products and services that consistently conform to requirements. As far as the ISO standard is concerned, organizations are required to act on the analysis and monitoring activity conducted as part of the performance evaluation process, outlined in clause 9, in order to continually improve the quality management system and in
turn enhance customer satisfaction. So let’s finish up the Mastering ISO 9001:2015 guide with the final clause of the standard, clause 10, Improvement.

It is fitting that we ended the previous chapter discussing the management review process because, if done right, will lead very nicely into the improvement stage. Along with internal audit, management review is probably the most effective way for the organization to evaluate its current system, and determine the best areas to focus on for improvement that will yield the most impactful results for customer satisfaction. Of course coming up with opportunities for improvement should not be restricted to the management review process alone, and should be a continuous activity. But the management review is a prime opportunity to really uncover the areas requiring improvement, and determining the best course of action in order to put improvement measures in motion. The ISO 9001 standard focuses on improvement affecting customer requirements and satisfaction. Which makes sense, since all action taken to improve any area of the organization's process is ultimately done in order to better serve its customers, and in turn enhancing the success of the organization.

In this chapter we will discuss the following sub-clauses of section 10, improvement, which are:

- 10.1. General;
- 10.2. Nonconformity and corrective action; and
- 10.3. Continual improvement.
10.1 General

Section 10.1 of the standard simply titled “General”, states that the organization must determine, and select opportunities for improvement, and implement any necessary actions to meet customer requirements and enhance customer satisfaction. Basically, find your opportunities, figure out what actions will be required to take advantage of them, and then make it happen. It’s completely up to the organization as to what opportunities they take advantage of, or how they go about doing it. The ISO 9001 standard simply states that the following areas must be considered at a minimum:

- The organization must focus on improving products and services in order to meet requirements, as well as to address future needs and expectations. Are there any areas where the organization is falling short on meeting the requirements of its products and services? This had better be a major focus for improvement. What will be required to close this gap, and ensure requirements are consistently met? How can the organization improve its performance in order to meet changing and evolving requirements, or customer needs such as increased demand for product, change in technology, or how a product or service is utilized? What can be done now in order to meet this requirement later?

- What processes have been put in place, or will need to be implemented in order to correct, prevent, or reduce undesired effects? Undesired effects could be almost anything that may impact the organization's ability to meet requirements, or operate efficiently. How will issues be dealt with when identified? Are there ways to further prevent undesirable effects from happening in the first place, or mitigate their effects when they do happen?
Lastly, the organization must focus on improving the performance and effectiveness of the quality management system. Again this is very general, but put simply, how can the system be improved? What processes will need to be revised, or enhanced? How can the system be made to be more efficient?

Things to look for:

- What steps are being taken to improve the system?
- Are corrective actions being raised and documented for following up?
- Is there evidence of innovation, or reorganization actions being implemented in order to streamline operations, or processes?

The key goal here is to show that the organization is monitoring and measuring its system and processes, performing analysis and evaluation, and using this information to improve. You can analyze and evaluate all you want, but it is of no value if the result of this evaluation is not acted upon for the betterment of the organization and its customers.

10.2 Nonconformity and corrective action

This next section can seem very straightforward and obvious on the surface, but many organizations struggle with effective processes revolving around non-conformance and corrective action. I mean of course you have to identify your problem areas and fix them, right? What's left to explain? But in fact many people struggle with the subtle differences between these two terms. So before we get into the specifics of what the ISO 9001:2015 standard requires in regards to non-conformance and corrective action, let's take a moment to clarify
in our minds just what these terms mean. Nonconformity is defined as a deviation from a specific procedure, standard, process, or system requirement. When defining nonconformities, it’s very important to identify the potential severity of the impact they could have on the organization or its processes. For example, a major nonconformity could be an existing or potential issue that will have serious consequences. A minor nonconformity would be less impactful to the overall operation or process, such as inaccurate documentation or records keeping. So essentially, a non-conformance is the actual issue that needs to be addressed.

A corrective action on the other hand is the action required or improvement measures needed in order to adequately eliminate or mitigate the nonconformity at its root cause. The last couple of words in the previous sentence – root cause – are extremely important to understanding the process of addressing non-conformance and implementing effective corrective action. You can easily fix an issue one day only to have it recur the next. This is an avoidable situation if the organization has a process in place to not only identify its non-conformances but also dig deep to find what caused it in the first place and fix it at the source.

Not all nonconformities are created equal, and some will require more attention than others. Once a non-conformance has been identified, the organization must determine the severity and if corrective action is required. You can certainly have nonconformity without corrective action. It may simply be a situation where the nonconformity does not pose a significant risk to the organization, or is deemed to be a one-time occurrence and is very unlikely to recur in the future and therefore it does not warrant the expenditure of resources in order to address it.
This leads us into the first requirement of section 10.2.1. Which states that when nonconformity occurs, including any nonconformity that arise from complaints, the organization must:

- React to the nonconformity appropriately. This is essential for an organization to survive. When you find a problem you must react. You cannot simply ignore your issues in hopes that they will take care of themselves. It’s up to you to take the necessary actions to address your nonconformities. How you react is up to you and the severity of that non-conformance. ISO 9001:2015 simply requires that you react to any nonconformity as applicable:

- Take action to control and correct it, which means develop corrective action;

- Or deal with the consequences of the nonconformity. Fix it or not, but if you choose not to implement corrective action you must be willing and capable of dealing with the consequences that such a nonconformity implies. If this is something that after careful deliberation would have a negligible impact on the organization or its products and services than it may make more sense to live with it and move on other than spending time and resources to eliminate.

I’ll also just touch on something that was mentioned in this part of the requirement that I feel is very important for organizations to properly address, and that is nonconformities that arise from complaints. You may be wondering what exactly the standard is trying to say here. Basically, if the organization receives a complaint from customers regarding their product or service, or if the operations of the organization are causing issue in other areas, such as with the environmental or social community, then they must recognize this as a non-conformance and deal with it accordingly.
Just because the issue is being generated from an outside source does not mean they do not require the same scrutiny and controls developed to address nonconformities that arise from within. In many cases these nonconformities can have a greater impact on the success of the organization.

- As we discussed earlier in this chapter, it’s one thing to identify a non-conformance, but it’s essential that organizations adequately evaluate the need for action to address the cause, or causes of that nonconformity, so that it does not recur or occur elsewhere. Root cause identification is vital to any nonconformity and corrective action process. Without it you are simply setting up the organization to make the same mistakes time and time again without ever addressing the real issue and learning from them. In order to do this effectively, and also meet the requirement of section 10.2.1, organizations are required to:

  ○ Review and analyze the nonconformity. This review and analysis allow the organization to determine the severity and implications arising from it. This will allow for more effective handling of the issue.

  ○ This review and analysis also helps to determine the cause of the nonconformity. As we have already discussed, this does not mean you take the nonconformity at face value. Otherwise you risk overlooking the actual underlying reasons for the nonconformity in the first place. It’s of course important to fix the immediate problem, but proper root cause analysis must be performed or you will continue to see the same issue time and again.
And the organization must also determine if similar nonconformities exist, or have the potential to occur. The original nonconformity should act as a flag. Now that you are aware of the non-conformance you are better equipped to identify similar issues and proactively address them. Do not allow the issue to exist in a bubble. Look at it from all angles and identify its potential to happen in other areas.

Now that the organization has identified the non-conformance and performed analysis to determined its severity and best course of corrective action to address both the immediate issue and the root cause, it's now time to:

- Implement the action needed. Assuming of course that after analysis you have determined it necessary to take additional action. It's usually a good idea to appoint someone with the responsibility and accountability to manage the corrective action required. Someone with knowledge and direct involvement of the area affected by the nonconformity. This individual will be accountable for implementing the actions necessary and coordinating with other individuals or functional departments that will be involved in the corrective action process.

- One area that is highly overlooked, but essential to any nonconformity and corrective action process is the review of the effectiveness of any corrective actions taken. It’s not sufficient to implement a corrective action and just assume that it has been effective and has adequately addressed the root cause. Follow-up of the effectiveness of corrective action will provide assurance that the root cause has been addresses and the likelihood of recurrence is low. Because every non-conformance and corrective action is different, the
time frame for review and follow-up will be highly dependent on the complexity of the corrective action process with respect to that specific set of circumstances.

- You will remember back in section 6.1 we discussed the requirement for organizations to consider and plan for risk and opportunity as well as the actions to address such risks. Well it's equally important to update this planning and implementation strategies addressing risk and opportunity should the non-conformance or implementation of corrective action have any effect on such planning. Remember the new 2015 standard has incorporated the risk-based thinking methodology into the very fabric of the new standard and therefore it is important to keep this mindset when making any type of change or adjustments to any area or process.

- The last requirement for section 10.2.1 is for organizations to assess and make changes to the quality management system when necessary. This requirement simply means that organizations must evaluate any processes or areas of the QMS that may be affected by the nonconformity or actions to address it and update those areas as needed. This is an important step in ensuring that the nonconformity does not recur. This could be in the form of updating a particular process, procedure or documentation in order to reflect the change.

So as you can clearly see, there is much more to the nonconformity and corrective action process than meets the eye and must be managed effectively. The corrective action must also be appropriate to the effects of the nonconformity encountered. Meaning if a complex nonconformity has been identified, the corrective action to address it will likely be a complex one as well, requiring time and resources and involving multiple parties. The same
can be said for a simple problem there is likely an equally simple and straightforward action to address it, which can be implemented rather quickly.

It may come as no surprise given the importance ISO 9001 places on identifying nonconformities and implementing corrective action, that the standard requires organizations to retain documented information pertaining to those nonconformities and actions to address them. The main reason for this is to provide evidence of:

- The nature of the nonconformity and any subsequent actions taken. What exactly was the problem? What effect did it have? What actions have been determined necessary to address it and have those actions been implemented.

- The other reason for this requirement is to show the results of corrective actions. Have the actions been effective and adequate to the issue. Did the organization actually follow through with the planned corrective actions? This also provides valuable information when performing follow up activities later to ensure the effectiveness and impact of the corrective action.

10.3 Continual improvement

Continual improvement should be at the forefront of every organization. It should be embodied in their objectives and quality policy. Without the drive to effect change and improvement of all processes that make up the quality management system an organization's growth potential can become stagnant. The primary goal of an effective QMS is to aid the organization in streamlining its output and to add value at every stage of production and operation. By continually improving the quality management system you are inherently improving the organization as a whole. But what is
Continual improvement anyway? Continual improvement is an ongoing set of activities performed in order to improve an organization's products, services or processes. These activities can be incremental over time or more substantial large-scale improvements. Every process within the organization's QMS should be subject to continual improvement processes regardless of the criticality or complexity.

Some of the methods for driving continual improvement have been discussed in detail throughout the standard and this book, such as internal audits, self-assessments and management review, so this is not a new concept. Along with these methods, the organization will use the results of customer feedback to drive continual improvement measures.

The final clause in the ISO 9001:2015 standard, 10.3 (continual improvement) states that the organization must continually improve the suitability, adequacy and effectiveness of the quality management system. Again as mentioned earlier, by improving the organization's quality management system, you are also improving the performance of the organization as a whole. So you can see why this would be an important concept within the standard. In order to accomplish this, the organization must consider the results of analysis and evaluation, which we discussed in clause 9.1.3, where the organization must analyze and evaluate data and information arising from monitoring and measurement activities. The organization must also take into consideration the outputs of management review. You will remember back in clause 9.3.2 that opportunities for improvement were both an input and an output to the management review process. The management review’s main goal is to drive improvement throughout the QMS and the organization. All of this analysis and review help the organization determine if there are needs or opportunities that must be addressed as part of the continual improvement process.
So that concludes this chapter on clause 10 (improvement) where organizations are required to continually improve the quality management system and its associated processes, and in turn enhance customer satisfaction. I cannot stress enough how important it is for organizations to act on the information available to them through the normal course of operations and continually examine its quality management system and processes to discover and eliminate problems, as well as identify areas of improvement. Any improvements made within the organization will ultimately reflect on the products or services they provide and make for a more satisfied customer.
ABOUT THE AUTHOR

Greg Peckford is the founder of QCAonline.com and is a corporate quality/health, safety and environment management professional with over 18 years' experience in areas of aviation, oil and energy, engineering and construction management.

Beginning his career as an aircraft maintenance engineer (AME) specializing in avionics working for various aircraft maintenance organizations (AMO’s) and major airline carriers in western Canada, Peckford eventually transitioned his career into engineering and construction management within the oil and energy sector where he currently resides as a Corporate Quality and HSE Manager.

In recent years, he has focused much of his attention on founding QCAonline.com, an online quality management training and consulting provider, specializing in helping businesses and professionals to implement and maintain a "value added" quality management system (QMS) that satisfies client requirements without the exorbitant expense, time commitment and resources needed to obtain formal certification to ISO 9001.

Gregory Peckford is a certified quality auditor and HSE administrator, holding certifications with Exemplar Global, ASQ (American Society for Quality) and ACSA (Alberta Construction Safety Association). He lives with his wife and 3 children in Calgary, Alberta Canada.
Gregory Peckford
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