ICAO RBIS QMS PROJECT

QUALITY MANAGEMENT SYSTEM

(ISO 9001 :2015)

AFI AIM RBIS QMS GUIDANCE FOR THE IMPLEMENTATION AND THE MONITORING OF THE QMS IN AERONAUTICAL INFORMATION MANAGEMENT

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ABBREVIATIONS

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CHAPTER 1. INTRODUCTION

1.1 Objective

The objective of this document is to provide guidance on how to develop and implement a Quality Management System (QMS) in the field of aeronautical information management (AIM).

There is sufficient evidence that a QMS can help to enhance the quality of AIM activities including streamlining and optimizing the processes and procedures applied and the products and services provided.

It is essential that this Guide is used in conjunction with the ISO 9001:2015 standard, which was published in September 2015, and which has fully replaced the ISO 9001:2008 standard since September 2018.

1.2 Scope

This guidance applies to any aeronautical information management provider for the State of [*State name*].

1.3 References

- *WMO n° 1100 : Guide to the Implementation of Quality Management Systems for National Meteorological and Hydrological Services and Other Relevant Service Providers (2017) ;*
- *ISO 9000 :2015, Quality Management Systems – Fundamentals and Vocabulary ;*
- *ISO 9001 :2015, Quality Management Systems – Requirements ;*
- *ISO 19011 :2018, Guidelines for Auditing Management Systems.*

1.3 Definitions

The quality management system (QMS) terminology, vocabulary and definitions used throughout this Guide are those of the International Organization for Standardization (ISO), in particular, those identified in ISO 9000 :2015, Quality Management Systems – Fundamentals and Vocabulary. The AIM and aviation terminology, vocabulary, abbreviations and definitions used are those of International Civil Aviation Organization and other relevant organizations as appropriate.

A brief description of the quality management terminology most frequently used is provided below :

Certification. Certification refers to the issuing of written assurance (the certificate) by an independent external conformity assessment body that it has audited a management system and verified that it conforms to the requirements specified in the relevant standard.

Control. Activities associated with ensuring a process provides consistent outputs at the required level of quality.

Customer. Clients and customers are usually referred to as “users”. However, the ISO family of standards exclusively uses the term “customer” in order to ensure clarity and consistency. It should be noted that a QMS may have internal and external customers.

External provider. Provider of products or services that is external to the QMS but which may be internal or external to the organization.

Input/output. An input is an element or component that is added to a process to assist in meeting a specified requirement (examples include data, materials, knowledge or competent staff). An output is a specific product or service that is expected to be produced by a process (examples include an aerodrome warning or forecast).

Integrated management system (IMS). Integrates all of an organization’s systems and processes into one framework, enabling the organization to work as a single entity with unified objectives.

Interested party. Any individual or organization that can affect the activities of AIM organization.

Stakeholder. Any individual or organization that can be affected by the activities of AIM organization.

Organization. Person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objective. That is, any AIM entity that develops and implements a QMS.

Quality. There are many definitions and interpretations of “quality”; however, all have one element in common: quality refers to the perception of the extent to which a

product or service meets customer expectations. It should be noted that quality has no explicit meaning unless it is related to a specific set of requirements. To highlight this, ISO defines quality "as the degree to which a set of inherent characteristics fulfils requirements".

Quality assurance. Aims to instil confidence that quality requirements have been met. It involves the systematic monitoring and evaluation of the processes associated with the generation of a product or service.

Quality control. Aims to ensure that quality requirements have been fulfilled prior to the dissemination of a product or the delivery of a service.

Quality improvement. Realized due to the successful development and implementation of a QMS.

Quality management (QM). A process that focuses not only on the quality of the product or service but also on the means to achieve it. It is centred on four activities: quality planning, quality control, quality assurance and quality improvement.

Quality management system (QMS). Organizational structure, procedures, processes and resources needed to ensure the delivery of an organization's products and/or services to its customers.

Service level agreement (SLA). A contract between a service provider (either internal or external) and a customer that defines the level of service expected from the service provider. As its purpose is specifically to define what the customer will receive, for instance in terms of timeliness, accuracy, resolution and frequency of issuance, an SLA is output based. It has the potential to be a key management tool for a QMS in terms of interactions with external providers.

Validation. Confirmation, through the provision of objective evidence that the requirement for a specific intended use or application have been fulfilled.

Verification. Confirmation, through the provision of objective evidence that the specified requirement have been fulfilled.

1.4 Drivers for adopting a quality management approach – International Civil Aviation Organization perspectives

The adoption of a QM approach to the delivery of AIM products and services was driven by a number of imperatives.
A key one was the International Civil Aviation Organization (ICAO) requirements relative to the delivery of aeronautical information services contained in RBIS AIM QMS regulatory framework.

1.5 The ISO 9000 family of standards

The ISO 9000 family comprises two kinds of QM standards : *requirements and guidelines*. The series consists of the following three standards, which represent international consensus on good QM practices :

a) **ISO 9000 :2015**, *Quality Management Systems – Fundamentals and Vocabulary*. This standard describes the fundamentals of QMSs and specifies the terminology used in ISO 9000.

b) **ISO 9001 : 2015**, *Quality Management Systems – Requirements* (ISO, 2015c). These requirements can be applied to all types of organizations, both in the public and private sectors, regardless of size or industry group. Therefore, they are generic in nature and can be adopted by, and adapted to, almost any organization ; this most certainly includes ICAO Member States and their AIM activities. They can achieve standards of quality that are internationally recognized and respected throughout the world. It is the only standard in the ISO family against which organizations can be certified (or registered), through a thirdparty audit process.

c) **ISO 9004 :2009**, *Managing for the Sustained Success of an Organization – A Quality Management Approach*. This standard focuses on achieving sustainable success in today's complex, demanding and ever-changing environment by meeting the needs and expectations of customers and other stakeholders. An interesting facet of this standard is that it promotes self-assessment as an important tool, which enables ongoing review of the level of maturity attained by QMSs. However, it should be noted that the self-assessment tool is not a substitute for a third-party audit process, which is fundamental to ISO 9001.

1.6 Importance of the ISO 9000 family of standards

1.6.1 The ISO 9000 family of standards, in particular ISO 9001, is important because of its international orientation. It has the support of national standards bodies from more than 160 countries and is therefore the logical choice for an organization such as ICAO. The ISO 9000 family of standards is also recommended to ICAO Members as a good practice. AIM providers operate in an international environment and have customers who demand an international standard of excellence.

1.6.2 The adoption of a QM approach to the delivery of products and services may require the implementation of a change management strategy. The ISO 9001 standard provides an appropriate framework to implement the required change management processes. The framework helps to identify the most-appropriate policies, procedures, records, technologies, resources and structures needed to achieve and enhance the quality of processes, procedures, products and services. The development and successful implementation of a QMS will instil a quality attitude at all levels of an organization, which, in turn, will help to ensure the delivery of products and services of an international standard.

1.7 Corporate governance and ISO 9001

1.7.1 In simple terms, governance relates to the processes and structures that ensure an organization is directed, controlled and held to account. It focuses on how an organization is managed, how risk is monitored and mitigated, and how value is added for the community,government and other stakeholders.

1.7.2 ICAO and its Members predominantly operate in a robust but often rigid public sector environment. The governance in these sectors covers a wide spectrum of activities focusing on how an organization meets the requirements of legislation and its government determined outcomes, how it expresses its culture and values, and how it discharges its stewardship responsibility by being open, accountable and prudent in decision-making, in providing policy advice as required, and in managing the delivery of programmes.

1.7.3 Good public-sector governance provides a foundation for high performance, strengthens community confidence in the organization and helps to ensure an

organization's reputation is maintained and enhanced. The key components and activities of a sound corporate governance framework are:

a) Promoting and ensuring adherence to a code of conduct and values;
b) Managing risk;
c) Providing continuity of service;
d) Ensuring work health and safety;
e) Ongoing development of staff competence;
f) Providing timely and accurate reports to senior/executive management including government and constituent bodies;
g) Contributing to the strategic and operational planning process.

1.7.4 An ISO 9001 QMS provides an excellent management tool to measure and monitor the ongoing performance of an organization's corporate governance activities. Seven key clauses of ISO 9001 enable the requirements articulated within them to be aligned with key corporate governance components. Adopting such a QMS enables the measurement of success or otherwise of corporate governance activities. Figure 1 provides a broad overview of this alignment.

Figure 1. Key clauses of ISO 9001 and their alignment with corporate governance activities

1.7.5 Standard ISO 9001 certification and registration

1.7.5.1 It is noted by ISO that “certification” refers to the issuing of written assurance (the certificate) by an independent external conformity assessment body that it has audited a management system and verified that it conforms to the requirements specified in the relevant standard (in this case, ISO 9001:2015). “Registration” means that the auditing body records the certification in its client register. Thus, the management system of the organization has been both certified and registered.
« Accreditation » refers to the formal recognition that an organization – termed either an « accreditation body » or « conformity assessment /certification body » – is competent to certify compliance with a specific ISO standard (for example, ISO 9001 :2015). Certificates issued by accredited conformity assessment/certification bodies are perceived on the market as having more credibility.

1.7.5.2 According to ISO, the certification process is expected to provide confidence that the organization has a QMS that conforms to the applicable requirements of ISO 9001. In particular, it is expected that the organization :

a) Has established a QMS suitable for its products and processes, and which is appropriate for its certification scope ;

b) Has analysed and understands customer needs and expectations, as well as the relevant statutory and regulatory requirements related to its products;

c) Has ensured that product characteristics have been specified in order to meet customer and statutory/regulatory requirements;

d) Has determined and manages the processes needed to achieve the expected outcomes (conforming products and enhanced customer satisfaction);

e) Has ensured the availability of resources necessary to support the operation and monitoring of these processes;

f) Monitors and controls the defined product characteristics;

g) Aims to prevent non-conformity and has improvement processes in place to:
   i. Correct any occurrences of non-conformity (including product non-conformity detected after delivery) ;
   ii. Analyse the cause of non-conformity and take corrective action to avoid its recurrence;
   iii. Address customer complaints ;

h) Has established an effective internal audit and management review process, and is continually improving the effectiveness of its QMS through monitoring and measuring.

1.8 Benefits of ISO 9001 certification

1.8.1 The benefits of implementing a QMS and achieving certification of compliance with ISO 9001 are significant. Below are some key benefits enjoyed by organizations with mature QMSs (not listed in order of priority):

a. Customer needs identified, met and monitored within a consistent management framework;

b. Improved management control and reporting;

c. Continuous improvement and enhanced quality culture embedded in the organization;

d. Clear processes in place to address poor-quality/non-conforming products;

e. Marketing tool for promoting the organization internally and externally, so that it stands out from potential competitors;

f. External audit by a third party, which is a powerful tool to establish and imbed the credibility and accountability of an organization;

g. Well-defined procedures and processes – employees know what to do and how to do it, and do not waste time duplicating efforts;

h. Enhanced teamwork, and internal and external communication;

i. Greater clarity of job specifications, descriptions and duties;

j. Improved work health and safety practices;

k. Greater quality assurance of products and services;

l. Enhanced response to customer feedback/complaints to rectify non-conformances;

m. The organization functions in a well-organized manner as a result of the systematic approach to the delivery of its products and services and associated activities;

n. As the QMS matures, more time is spent on improving products and services, as opposed to rectifying, and reacting to the demands of dissatisfied customers;

o. Significant decreases in time and money spent on recurring problems, as many are resolved permanently;

p. The organization builds the inner resources and skills necessary to identify and resolve problems more expediently;

q. Significantly improved documentation processes and procedures that, in turn, enhance the capture of corporate knowledge;

r. Improved document control, which enhances the ability of the QMS to produce high quality responses to the legal community on matters pertaining to requests such as those associated with accident/incident investigations and insurance claims;

s. Competencies are identified, gained and maintained through appropriate training;

t. Job satisfaction of employees can be significantly improved;

u. The QMS is a powerful change management tool;

v. The QMS is a powerful tool to ensure important issues are highlighted at the appropriate organizational level;

w. Although no longer a requirement of ISO 9001, those QMSs already maintaining a quality manual have identified it as a useful induction tool for new staff and as a road map for how the QMS operates;

x. Risk-based thinking – identifying opportunities and threats;

y. Control and monitoring of externally provided processes, products and services;

z. Enhanced understanding of the context of the organization – internal and external issues that affect it.

1.8.2 The adoption of a QM approach and certification of compliance with ISO 9001 can deliver a vast range of benefits. However, it should be remembered that the achievement of ISO 9001 certification of compliance is not an end in itself – it is a milestone in the QM journey.

1.9 Standards and publications of the International Organization for Standardization

It is essential that AIM organizations adopting a QM approach to their activities and the delivery of products obtain copies of:

a. ISO 9000:2015, *Quality Management Systems – Fundamentals and Vocabulary*;

b. ISO 9001:2015, *Quality Management Systems – Requirements*;

c. ISO 19011:2018, *Guidelines for Auditing Management Systems*.

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CHAPTER 2. PRINCIPLES OF QUALITY MANAGEMENT

2.1 Overview

The principles of QM underpin the ISO 9000 standards and need to be embedded in a QMS to provide a sound foundation for achieving the goals and objectives of AIM organizations.

2.2 Principles

2.2.1 A QM principle is a fundamental rule for leading, operating and developing an organization, with the objective of continually improving performance over the long term through a focused approach to all stakeholders, particularly customers. There are seven principles of QM that provide a sound foundation for achieving goals and objectives.

2.2.2 Standard ISO 9001:2015 is based on the seven principles of:

- Customer focus
- Leadership
- Engagement of people
- Process approach
- Improvement
- Evidence-based decision-making
- Relationship management

2.2.3 As mentioned in paragraph 1.5 above, the ISO 9001:2015 standard can be applied to virtually any organization, as can the principles. It is therefore not appropriate within the context of this Guide to attempt to articulate how they should be applied. Each organization will need to apply the principles in terms of their own particular activities. Fortunately, ISO has produced an extremely informative and contemporary document, which provides, for each principle, a description, an explanation of the rationale as to why it is important, and examples of the key benefits and actions that can be taken to improve performance when applying the principles (ISO, 2015c, section 0.2).

2.2.4 It is a useful exercise for organizations adopting a QM approach to review and document their activities in the context of these principles.

2.3 Process approach – the plan, do, check, act (PDCA) cycle

2.3.1 Fundamental to ISO 9001:2015 is a process approach that has been highlighted as one of the principles of QM. The plan, do, check, act (PDCA) cycle provides a methodology to assist in the development and implementation of this approach.

2.3.2 The PDCA cycle is an iterative four-step management process typically used in organizations that implement QM. It can be used to coordinate the efforts of AIM organizations to continually improve work processes. It emphasizes and demonstrates that improvement programmes must start with careful planning, must result in effective action, and must move on again to careful planning in a continuous cycle. Figure 2 illustrates this process.

2.3.3 The development of a QMS within the ISO 9001:2015 framework will enable AIM Organizations to use the process approach, coupled with the PDCA cycle and risk-based thinking, to align or integrate QMSs with the requirements of other management system standards. These PDCA cycles can be applied to many levels within an organization and its activities.

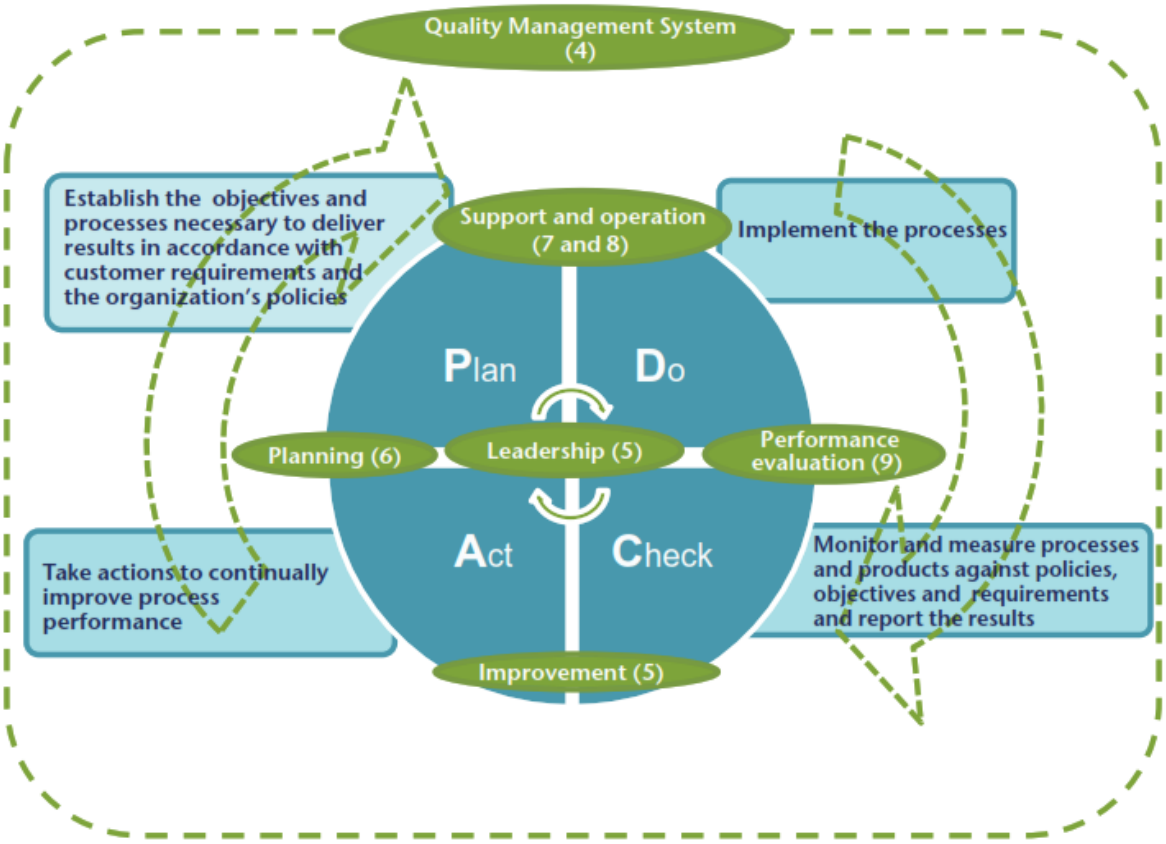

Figure 2. The PDCA cycle

2.4 Risk-based thinking

In a departure from its predecessor ISO 9001:2008, references to preventive action in ISO 9001:2015 have been removed. However, the core activity of identifying and addressing potential risks to the organization still remains. AIM Organizations must be able to demonstrate that they have identified, considered and taken action (as appropriate) to mitigate any risks and capitalized (as appropriate) on any opportunities that may affect their organization. The approach to risk must be proportionate to the consequences, should the risk be realized.

2.5 Explanatory notes

Table 1 provides explanatory notes and insights into the intent of standard ISO 9001 on a clause-by-clause basis. It is imperative that users of this Guide read the table in conjunction with standard ISO 9001:2015, to ensure a full understanding and appreciation of each clause.

Table 1. Explanatory notes for clauses from standard ISO 9001 :2015

Requirements	*Guidance notes*	*Hints and resources*
4.1 Understanding the organization and its context	There are many internal and external issues that affect, or have the potential to affect, the QMS. It is imperative these are identified so that there is clear understanding and appreciation of the operating environment. These perspectives are clearly articulated in the standard, and include technological, legal, market, economic and cultural issues. Notes 1 and 2 of the clause provide a broad framework within which to identify and assess the context. Understanding the context and formally addressing identified issues will help to ensure ongoing viability and credibility of the QMS.	The environmental scanning tool, which is broadly based on the traditional strengths, weaknesses, opportunities and threats (SWOT) analysis, provided in Appendix 1 to this Guide should be used. It is important that each step of the tool is followed, in particular, to ensure the issues identified are addressed as part of the planning process and that any risks identified have a formal risk mitigation strategy. The environmental scan will assist in determining the QMS scope as required under clause 4.3. The environmental scan and follow-up actions will also provide clear evidence of a comprehensive process undertaken to understand and react to the context within which the organization operates.
4.2 Understanding the needs and expectations of interested parties	Interested parties are stakeholders – any individual or organization that can affect the QMS, or any individual or organization that the QMS can affect. In both cases, the effect can be negative as well as positive. It is important that any statutory or regulatory requirements associated with interested parties are identified and addressed by the organization, as appropriate.	The first task in meeting the requirements of this clause is to identify all the QMS stakeholders/interested parties. A simple but comprehensive stakeholder analysis should be performed. A stakeholder analysis template is provided in Appendix 2. Stakeholder analysis will also provide useful information that will further underpin the requirements of clause 4.3 and subclauses 5.1.2 and 9.1.2.
4.3 Determining the scope of the quality management system	Definition of the scope is a key component of a QMS. It provides the boundaries as to what is within the scope when it comes to developing, implementing and auditing the QMS. The scope is usually meticulously articulated on the certification of compliance to ensure there is absolutely no confusion as to what sections and activities of the QMS are certified as following ISO 9001:2015.	The environmental scanning (see Appendix 1) activity will provide useful input into defining the scope of the QMS. It must be ensured that there is no ambiguity in terms of the scope. There must be no circumstances under which a section/area outside the QMS scope can be interpreted or inferred to be covered by the certification. The scope can be changed, but in terms of certification, this should be done in close consultation with the conformity assessment/certification body. Any changes to the scope should be subject to the requirements under the standard and subject to audit by the conformity assessment/certification body who would confirm, or otherwise, the inclusion of the change under the certification.
4.4 Quality management system and its processes	It is imperative that the organization has established a demonstrable process-based QMS. In line with other clauses within the standard, the QMS will need to be maintained and monitored. This clause clearly	There is now a greater focus on the QMS processes and the associated documentation. The process matrix template in Appendix 3 provides a useful tool for identifying and addressing the requirements of this clause. It provides useful evidence for demonstrating the processes that underpin QMS activities.

Requirements	*Guidance notes*	*Hints and resources*
	articulates the high-level requirements for the design of a process-based management system, under subclause 4.4.1.	It is also a useful planning tool in terms of providing input into the requirements of other clauses including those associated with risk, planning, resources, and the monitoring and measuring of outputs of the QMS. The process matrix can be a useful artefact to present at audit.
5.1 Leadership and commitment 5.1.1 General	Standard ISO 9000:2015, subclause 2.3.2.1, states that "Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the organization's quality objectives." Standard ISO 9000:2015, subclause 3.1.1, defines "top management" as a "person or group of people who directs and controls an organization at the highest level … Top management has the power to delegate authority and provide resources within the organization." Top management is expected to demonstrate leadership and commitment to the QMS and accountability for its ongoing sustainability. Top management must be able to clearly demonstrate practical involvement in leadership of the QMS. An often-used phrase in the QM community relevant to this clause is that the "video needs to be in sync with the audio". That is, words alone will not suffice; they must be backed up with clear decisive actions that demonstrate meaningful support for the QMS.	It is appreciated that this may present a daunting task for the QM professionals developing and implementing a QMS for their organization. However, there are some effective activities that can involve top management and which enable it to provide some positive and practical inputs. Top management should be provided with a comprehensive briefing on QM that includes a broad overview of ISO 9001:2015. During the top management briefing, an in-depth explanation of roles and responsibilities under clause 5 should be provided, to ensure that management has a thorough understanding and appreciation of what is involved. Top management should be provided with a draft quality policy that can be modified as appropriate and endorsed. It is imperative that management fully understand and appreciate the requirements under clause 5.2. Appendix 4 provides examples of quality policies that may be useful for adapting to the QMS. It should be ensured that members of the top management chair the quality management review meetings (QMRMs). This provides useful insight into the grassroots processes and enables management to respond accordingly. It is imperative that management fully understands and appreciates the requirements under clause 9.3 and subclauses 9.3.2 and 9.3.3. The insight that top management receives during QMRMs will provide useful input into the QMS planning processes. See clause 6. It is absolutely critical that top management is well prepared for audits, both internal and external. This will ensure a successful audit result. The need for this cannot be emphasized enough. The QM professional who has responsibility for development and implementation should provide a coaching/mentor role for top management. A good starting point is to provide a comprehensive briefing on the audit process and give a sense of the questions that may be encountered. Appendix 5 provides a useful overview and examples of questions that may be asked regarding the role of top management in the QMS. These should be reviewed with top management, to ensure it is familiar with the context of each question.
5.1.2 Customer focus	Top management is now required to take the lead role in demonstrating QMS commitment to customers. In particular, customer requirements and statutory and regulatory requirements must be identified, understood and consistently addressed. Any potential risks that threaten continuity of services and products, and the level of customer satisfaction, should be mitigated.	This is not a one-off activity for top management but one that will underpin ongoing levels of customer satisfaction and continuous improvement. The key to addressing the requirements of this clause is identifying and meeting customer needs, and, wherever possible, exceeding their expectations. An excellent first step is formally identifying and documenting those needs so they can be monitored and measured. Appendix 6 provides a useful template for achieving this. The development and implementation of a documented, scheduled review of requirements process is a useful component of Appendix 6. It provides evidence to demonstrate how subclause 8.2.3 is being addressed.

Requirements	*Guidance notes*	*Hints and resources*
	In addition, top management must also ensure the QMS remains focused on delivering conforming products and services, on meeting its statutory and regulatory obligations and on enhancing customer satisfaction.	Establishing levels of customer satisfaction as per subclause 9.1.2 should be undertaken in conjunction with reviewing of customer requirements. Identifying and meeting the requirements not stated by the customer are often key elements to success. Taking the time to clearly identify customer needs is important and is underpinned by experience of working with the customer base. The positive results that can be obtained are well worth the effort.
5.2 Policy 5.2.1 Establishing the quality policy	The quality policy is a key document of the QMS. Subparagraphs 5.2.1(a)–(d) set a clear framework for the policy and should be adhered to. It is important to note that there is emphasis on the quality policy being appropriate to the organizational context and strategic direction, as well as to the purpose of the QMS. The quality policy will also provide a broad framework for setting QMS objectives. Top management needs to lead the establishment, creation, review and ongoing maintenance of a quality policy that is relevant to activities.	As stated previously, top management should be provided with a draft quality policy that can be reviewed as appropriate, and it should be ensured that it fully understands and appreciates the requirements under this clause. Appendix 4 provides examples of quality policies that may be useful for adapting to the QMS. The QMS context and strategic direction should have already been established in clause 4.1, and it should therefore be readily articulated into the quality policy. Remember any change in strategic direction will require a review and an amendment to the quality policy, as appropriate. Review the quality policy on a scheduled basis (yearly) for its continued suitability and viability.
5.2.2 Communicating the quality policy	The quality policy must now be readily available to stakeholders and the QMS, and it will need to be carefully considered how this is done.	A powerful way to communicate the quality policy is to post it on the website. It is also essential that top management's verbal commitment in meetings, internal conferences and so forth is clearly articulated. There is also merit in validating, during QMRMs, that any proposed changes to the QMS still align with the quality policy. If not, a review of the policy and the proposed changes should be undertaken and documented as part of the minutes of QMRMs.
5.3 Organizational roles, responsibilities and authorities	Many avoidable errors and much wasted time will occur in a QMS when employees are not clear about what they are responsible for and what decision-making power they have. Top management must ensure that responsibilities and authorities are defined and communicated within the QMS. Responsibilities and authorities of each employee should be clearly defined and be available to all staff. Although there is no longer a requirement for a QM representative, there is a new requirement for top management to ensure that someone is tasked with preserving the integrity of the QMS while planning and undergoing change. See subclause 5.3(e).	Inevitably, some QMSs do not regularly review and update job descriptions and associated duty statements. Scheduled reviews of job descriptions should be clearly articulated, in particular, when a position is advertised as a vacancy. A traditional organization chart is still an excellent tool for illustrating reporting lines, but it is imperative that it is kept up to date, on both hard and soft copy. Auditors frequently use the organization chart as a starting point for an audit because it should clearly illustrate the scope of the QMS. A focus of ISO 9001:2015 has been to integrate QM activities across the QMS through the removal of the management representative role requirement. These activities include ensuring QMS processes are established and maintained, reporting of QMS performance and focusing on customer requirements. In reality, mature QMSs have already integrated these activities as part of their business as usual. Providing a QM duty in job descriptions and duty statements has proven to be an effective way of achieving this. Appendix 7 provides some examples of how this can be performed for various levels within an organization.

Requirements	*Guidance notes*	*Hints and resources*
		It is no longer a requirement of ISO 9001:2015 to have a QM representative. However, experience has clearly demonstrated that as a QMS matures, this is not the case. A QM professional is required to ensure the ongoing sustainability, viability and integrity of the QMS. In fact, subclause 5.3(e) highlights the need to ensure this occurs as part of planning and undergoing change (see section 5.3 of this Guide).
6.1 Actions to address risks and opportunities	This clause reflects a key outcome from clause 4.1 when establishing the context of the QMS. Determining the risks and opportunities flows directly out of that process. Addressing the risks (in particular) and opportunities will ensure the QMS achieves its planned objectives. Note 1 of this clause provides options for mitigating risks and note 2 provides methods for capturing opportunities and potential outcomes. Subclause 6.1.2 highlights the need for a planned approach, that the associated actions should be integrated into the QMS and that their effectiveness should be evaluated.	Although developing and implementing a formal risk management process is not a requirement, due consideration should be given to using ISO 31000:2009, Risk Management – Principles and Guidelines (ISO, 2009*b*), to underpin how risk is addressed. It is therefore strongly encouraged that identification and management of risks be formally undertaken and documented. Risk management can be defined as the identification, assessment and prioritization of risks. However, the most important aspect is to mitigate the risks using appropriate resources to monitor and minimize any potential impacts on the QMS. It is strongly recommended that formal training in risk management be undertaken. There can be a tendency to only focus on risk, and in doing so, miss the possibility to capitalize on identified opportunities. The register in Appendix 2 helps to ensure opportunities that are identified – especially as part of the environmental scanning process – are captured and, where possible, capitalized on. The register is comprehensive and has proven to be a useful and practical QM tool.
6.2 Quality objectives and planning to achieve them	This clause requires QMSs to set quality objectives for relevant functions, levels and processes within the organization. It is important to ensure that that the quality objectives and associated key performance indicators (KPIs) are consistent with the quality policy (see clause 5.2), are relevant to the products and services, and demonstrate they are meeting or exceeding customer expectations. Subclauses 6.2.1 and 6.2.2 provide clear requirements in terms of the quality objectives and how to achieve them. It should also be noted that any externally provided processes, products and services may also require quality objectives (see subclause 8.4.1).	Organizational planning activities affect several areas within the QMS, and it is imperative to ensure this activity is comprehensively undertaken and well documented. It is important that QMS objectives are validated against any higher level strategic and/or corporate planning objectives to ensure their alignment with the broad QMS direction. When developing KPIs, it is important that they are realistic and meaningful in terms of providing useful insight into the performance of the QMS in meeting its identified objectives. For example, a KPI that states "the publication of 100 NOTAM" is meaningless in terms of the quality and usefulness of those forecasts. More-informative KPIs in terms of performance would be, for example, "95% of NOTAM published in the scheduled time". It is important to ensure KPIs are meaningful to all key stakeholders including the customer(s), top management, supervisors and the staff who actually produce the products and services. Using input from the staff who produce the products and services involved in determining KPIs is a sound management strategy that will have significant benefits in terms of buying in to a QM approach. The environmental scan (Appendix 1) and the outcomes from that process, combined with the process matrix (Appendix 3), provide a useful source and a good starting point for formulating quality objectives.

Requirements	*Guidance notes*	*Hints and resources*
6.3 Planning of changes	When changes to the QMS are required, they must be performed in a planned and systematic manner. Due consideration should be given to what the change is trying to achieve and any potential consequences (positive or negative), while ensuring that the overall integrity of the QMS is maintained. Other issues that need to be considered include whether there are sufficient resources available and the potential impact on any roles and responsibilities. Documented information needs to be retained relating to planned changes and their potential impact on the QMS.	One of the most important aspects of this clause is documenting planned changes. It should be noted that under subclause 9.3.2, there is a requirement that changes are an important input. Having any changes that may affect the QMS as a standing agenda item of QMRMs is a good way of ensuring this happens.
7.1 Resources 7.1.1 General	This clause focuses on the requirement for the QMS to determine the resources (internal and external) required for implementation, maintenance and continuous improvement. The subclauses of 7.1 have specific focuses on people (7.1.2), infrastructure (7.1.3), environment for the operation of processes (7.1.4), monitoring and measuring resources (7.1.5) and organizational knowledge (7.1.6).	When determining resources, it is important to ensure they are aligned with the quality objectives endorsed by top management. The importance of obtaining the appropriate level of resources to support the ongoing viability and improvement of the QMS should be emphasized. The importance of obtaining the appropriate level of resources to either achieve or maintain the certification of compliance to ISO 9001:2015 should also be emphasized.
7.1.2 People	This subclause focuses on ensuring the appropriate staff is available for effective operation of the QMS. This also includes ensuring there is adequate staff to meet customer and applicable statutory and regulatory requirements.	Meeting identified customer needs and ensuring a high level of customer satisfaction (subclause 9.1.2) is a significant driver for ensuring levels of appropriately qualified/competent staff. Ensuring applicable national and international statutory and regulatory requirements are met is another significant driver for having correct levels of appropriately qualified/competent staff.
7.1.3 Infrastructure	The requirements for this subclause focus on identifying, providing and maintaining the infrastructure resources to ensure processes operate effectively. Examples are provided on what is considered for inclusion as infrastructure.	Lack of appropriate infrastructure can significantly undermine the viability of the QMS. It is recommended that any issues or concerns relating to infrastructure be identified via means that include section/staff meetings and other organizational forums, including internal and external audits. If they have been identified and there is a well-documented and appropriately resourced plan in place, it should not be a major issue. In fact, it demonstrates that the QMS is working. It must be remembered that the QMS is a dynamic real-life organizational entity within which things can and do go wrong. Therefore, things cannot be perfect all of the time – even during an audit.
7.1.4 Environment for the operation of processes	This subclause focuses on the organization's need to "determine, provide and maintain" a suitable environment for the operation of processes.	The comments made above under subclause 7.1.3 apply just as readily to this subclause. Most importantly, a documented process that identifies potential or current issues and articulates a procedure to rectify any issues as quickly as possible should be in place.

Requirements	*Guidance notes*	*Hints and resources*
	This subclause notes that a suitable environment can be a combination of physical, social, psychological, environmental and other factors, including temperature, cleanliness, prevention of staff burn out, etc.	The internal audit process may identify issues, as will a work, health and safety culture embedded within the QMS.
7.1.5 Monitoring and measuring resources 7.1.5.1 General	This subclause focuses on monitoring and measuring activities to demonstrate that products and services conform to requirements. There must be an appropriate level of resourcing to assure that the monitoring and measuring is suitable for the activity and will provide valid and reliable results. It is also important to ensure that the resources needed for monitoring or measuring are maintained to a standard that is fit for purpose. Appropriate documented information (records) must be maintained.	It should be ensured that all monitoring and measuring equipment documentation is up to date and readily available. It should also be ensured that all monitoring and measuring records are kept up to date and are readily available to appropriate staff. It should be ensured that the results of monitoring and measuring are periodically reviewed on a scheduled basis and that there is a documented process in place to address any identified issues. All of the above apply to both external and internal providers.
7.1. 5. 2 Measurement traceability	This subclause focuses on providing confidence that measuring equipment has been calibrated against international or national measurement standards. There must also be documented traceability that clearly articulates when and how equipment has been calibrated and to what standard. The “when” can be at specified intervals or prior to use. The need to protect measuring equipment from damage and to ensure its ongoing integrity is highlighted. This subclause states that if national or international standards do not exist, then the organization must have documented information detailing the underlying basis used for the calibration or verification of the measuring instrument. It also states the action necessary to be taken if equipment has been found unfit for purpose.	Comprehensive and well-maintained documented records are key to meeting the requirements of this subclause.
7.1.6 Organizational knowledge	The focus of this subclause is to ensure the organization captures and preserves knowledge, which underpins processes and ensures the quality of products and services.	The ongoing need to reassess and establish the needs of the organization is closely linked to other requirements of ISO 9001:2015. Clause 4.1, for example, addresses the context of the organization within the environment in

Requirements	*Guidance notes*	*Hints and resources*
	It emphasizes the need to ensure that the knowledge is contemporary in that it reflects current needs and trends; if not, the additional knowledge should be obtained. Two notes associated with the subclause provide clarification on what organizational knowledge is and that it can be based on internal and external sources.	which it operates. As that environment changes, it is essential to ensure the appropriate organizational knowledge is maintained or acquired. Using the environmental scanning tool (Appendix 1) on a scheduled basis (for example, annually just prior to the organization's planning process) provides an excellent opportunity to reassess the level of organizational knowledge. Another opportunity to establish or reassess the organizational knowledge is when establishing customer needs. See subclauses 5.1.2, 8.2.2, 8.3.6 and 9.1.2. Clause 8.4 provides the organization with the opportunity to consider knowledge required "in-house" to influence and control external processes. This may require appropriate training of specific staff.
7.2 Competence	Establishing and documenting levels of competence is a key clause and is fundamental to the organization. Once determined, the organization must then ensure the staff is competent through appropriate education, training or experience. If competence needs to be acquired, the organization must take the appropriate action to do so. A follow-up evaluation of the effectiveness of the action taken needs to be documented. Documented evidence of competence is also a requirement. It is important to note that that "people doing work under its control" will include contractors and the staff of external providers to which work has been outsourced. Subclause 8.4.3 also makes specific reference to this under subparagraph (c).	Standard ISO 9000:2015 defines competency as the ability to apply knowledge and skills to achieve intended results. After establishing the level of competence required with each position in the QMS, there is merit in undertaking a simple competence needs analysis for each staff member. This will provide the QMS with a comprehensive overview of the competence profile and provide excellent evidence for audits. Appendix 8 provides a simple template to adapt for this purpose. Once the required level of competence is identified, the job description documentation for each position should be reviewed and amended as appropriate, to reflect the requirements. There is also merit in establishing a competence review period (for example, every 3 years).
7.3 Awareness	Awareness has been elevated to a clause in its own right. It should also be noted that as with clause 7.2, it applies to all "persons doing work under the QMS's control". Subparagraphs (a)–(d) of the clause state employees shall be aware of quality policy, the quality objectives, their contribution to the effectiveness of the QMS and the implication of not conforming.	The requirements of this clause mean that it is incumbent for the QMS to ensure "all persons doing work under it" are fully briefed on the QMS. It would be prudent to have these as key components of the QMS induction process for new staff (including contractors). It would also be practical to document the induction and ensure it is signed off by inductees for several reasons, including evidence for an auditor. Clearly, this also requires a healthy degree of common sense in terms of the level of engagement and the potential impact that contracted staff may have on the QMS.
7.4 Communication	This clause focuses on all internal and external communication relating to the organization's QMS. The clause clearly articulates, in subparagraphs (a)–(e), specific requirements for internal and external communication.	The development of a communications plan for the QMS will greatly assist in meeting the requirements of this clause. Internal/ external communication lines can easily be identified if a mature management system has been established.

Requirements	*Guidance notes*	*Hints and resources*
	It should be noted that there is a customer specific communication subclause (8.2.1), which also needs to be addressed.	Additional information for internal communication can also be found in service level agreements (SLAs) between departments/programmes. External communication should include communication based on contracts and information about status of the service. An example of a diagrammatic communications plan is provided in Appendix 9 as a template for adaption if required.
7.5 Documented information 7.5.1 General	Subclause 7.5.1 includes all documented information identified as a requirement of ISO 9001:2015 and that required for the effective operation of the QMS. The subclause notes that the extent of documented information can differ between QMSs due to their size, complexity, products and services, and competency of staff.	There is no longer an explicit requirement for a quality manual as per ISO 9001:2008 requirements. However, experience has shown that operators of mature QMSs have expressed a strong desire to maintain the quality manual, because it is an ideal induction tool and provides a road map as to how the QMS works. A procedure for documenting information would also be beneficial. Reviewing and, as appropriate, amending a current 2008 quality manual to reflect the 2015 requirements has the benefit of giving the reviewer an enhanced understanding and appreciation of the new standard. In the early stages of development and implementation, QMSs are opting for specific dedicated QM web pages that take the place of a quality manual and have proven to be effective. It must be remembered that any web-based documented information, in particular operational processes, need to be secure. The development of a detailed documented process that clearly delineates lines of authority for changing processes (particularly online) and notifying stakeholders is imperative for the QMS.
7.5.2 Creating and updating	This subclause focuses on ensuring documented information that is created or updated is appropriately identified, described, reviewed and approved. Subparagraphs (a)–(c) clearly articulate the requirements.	The use of document control panels and the use of headers and footers are ideal for document identification. Online QM pages also require identification of and information on the currency of the document and updates. These elements should be included in any QM web-page design
7.5.3 Control of documented information	The subparagraphs under subclauses 7.5.3.1 and 7.5.3.2 clearly articulate the requirements in terms of control of documentation. It is also stated that documented information from external sources that is used as part of the planning and operation of the QMS must be identified and controlled.	Auditors will focus on the permissions to access documentation and, more importantly, who has the authority to change or approve changes to documentation. Who has the authority on changes and approvals needs to be clearly documented and reflected in a document control panel. This also includes a check of the documented information to ensure it is up to date and protected against improper use. Maintaining the integrity of documentation extends to web-based documentation such as wiki pages. Therefore, the control of documented information must be reflected in the web-based environment, in particular, for operational documentation such as SOPs.
Clause 8 – Operation		
8.1 Operational planning and control	This clause articulates the requirements for the planning, implementation and control of processes.	The information obtained from the environmental scanning tool (Appendix 1) can provide useful input for addressing this clause.

Requirements	*Guidance notes*	*Hints and resources*
	The clause is strongly linked to the requirements addressed in several clauses, in particular, clauses 4.4, 6 and 8.4.	The suggested process matrix in Appendix 3 can provide useful input into how the requirements are being addressed. It should be ensured that any identified risks are reflected in the risk register. Control of externally provided processes, products and services has the potential to present some unique challenges, which are addressed under clause 8.4.
8.2 Requirements for products and services 8.2.1 Customer communication	Subclause 8.2.1 focuses on QMS communication with customers. There is a clear link between subclause 5.1.2 and clause 7.4. The subparagraphs of subclause 8.2.1 clearly articulate the requirements for customer communication.	Meeting customer identified needs is a key objective and it is therefore imperative to clearly identify and understand the needs of the QMS customer base. For example, customers can also be found within an organization, and there are different ways of accessing information on products and services. Web-based provision of products and services is common for aviation. It is highly recommended that, at the very least, a simple customer register be developed that identifies customer names, community sectors they are from (for example, aviation, marine, agricultural or the general public), products and services the QMS provides to the customers and frequency with which the needs of the customer are reviewed. It is important for all staff involved in the provision of products and services to understand the potential impact (positive and negative) on customer operations. Appendix 6 provides a simple template for this purpose. It is appreciated that some QMSs may develop comprehensive databases, and the template is only presented as a starting point for consideration. A key customer communication strategy is a scheduled review of the current products and services provided. It is strongly recommended that a review schedule be developed and documented. Apart from being a useful planning tool, it has the additional benefit of providing evidence for audit purposes. There is considerable value in integrating the requirements under subclause 8.2.1 into the communications plan (Appendix 9).
8.2.2 Determining the requirements for products and services	This subclause focuses on determining the requirements for the customer products and services. The subparagraphs clearly articulate the requirements. Identification of any applicable statutory and regulatory requirements in terms of the products and services being offered is crucial. Ensuring the QMS can meet the claims that it makes on the products and services it intends to offer is vital to the ongoing credibility of the QMS.	The development of proposed customer records (see Appendix 6) offers the ideal opportunity to address the requirements of this subclause.

Requirements	*Guidance notes*	*Hints and resources*
8.2.3 Review of the requirements for products and services	This subclause focuses on reviewing the requirements for products and services. The subparagraphs under subclauses 8.2.3.1 and 8.2.3.2 clearly articulate the requirements. The requirements state the QMS needs to be reviewed to ensure it can provide the products and services prior to committing to them. Subparagraph (b) highlights that consideration should be given to any requirements not expressly stated by the customer but which may be known to be necessary for the product or service to be fit for purpose and meet customer needs. It is important that all reviews of customer requirements are documented and retained and that any changed requirements to products and services are communicated to relevant stakeholders.	As stated previously, a documented scheduled review of product and services requirements for customers is strongly recommended and can be useful. The development of proposed customer records (see Appendix 6) and the subsequent interaction with the customer offer the ideal opportunity to address the requirements of this subclause. It is appreciated that identifying the customer when the general public is the customer can be challenging. However, innovative approaches such as face-to-face meetings, specific focus groups and user groups provide invaluable feedback and input for addressing the requirements of this subclause. Useful feedback can also be obtained from online surveys, which can be developed for the general public/community feedback or for specific user groups. It is strongly recommended that considerable care be taken in developing survey tools to ensure they provide the level of feedback that is being sought.
8.2.4 Changes to requirements for products and services	This subclause focuses on the relevant action being taken when requirements are changed to ensure key stakeholders are informed.	The advising, to key stakeholders, of changes in requirements, in particular staff who provide the products and services, has the potential to be contentious. For example, within a 24-hour shift-work environment, managers will not always have the opportunity to pass on information relating to any operational changes to products and services face to face. Email advice is one method that is frequently used in today's operational environment. The "request a delivery receipt" and/or "request a read receipt" email tracking are options. However, neither guarantees that the recipient, although having received the email, has read and understood the changes, which, in the operational environment, could be critical. An incident/accident resulting from the failure to make a significant operational change can have serious consequences – especially if the staff member who issued the product had received notification by email. It would be difficult for the manager/supervisor who advised of the change to confirm the change required was understood by the staff member who issued the product. It could be argued that receiving the email and understanding the required changes or seeking clarification is an expectation as part of the professionalism associated with issuing a product. However, human factors need to be taken into consideration, and management/supervisory staff and operational staff are potentially exposed, especially if there is an enquiry or investigation related to an incident. It is highly recommended that due consideration be given to how this issue can be addressed. The potential incident scenario (referred to above) can be addressed through the use of a reading log. The manager/supervisor sends an email advising of a change to a product or service. The shift-work staff members

Requirements	*Guidance notes*	*Hints and resources*
		are given a specified number of days to sign a simple reading log which acknowledges that they have read and understood the required change(s). Shift supervisors are required to check on a shift-by-shift basis the status of the reading log and that any staff on duty have read and signed it. It is strongly recommended to announce changes well in advance, to give employees enough time to prepare. Sometimes, just informing via email is not sufficient, and a training session may well be the most appropriate way. The above provide effective key procedures that satisfy audit requirements under this clause.
8.3 Design and development of products and services 8.3.1 General	This clause focuses on the QMS establishing, implementing and maintaining a design and development process that is appropriate to the provision of products and services.	It is appreciated that the design and development of products within the environment of AIM can be different to that of other QMSs. However, this clause and its associated subclauses provide a useful framework for development and design activities. However, a QMS that develops specific templates to meet needs will need to ensure that all of the requirements of this clause (in its totality) are included. To address the requirements, it is strongly recommended that a project template approach be adopted. There are commercial "off-the-shelf" software packages available (for example, PRINCE2) that can be readily adapted for this purpose. A project control should be established, and the verification and validation phases clearly highlighted. Validation follows verification to prove that the design of a product or service has worked in practice. The greater the risk associated with the product, the more extensive this validation should be. The role of this Guide is not to provide methodologies for validation and verification. However, it is strongly encouraged that contemporary validation/verification methodologies be adopted to assist in meeting the requirements of these clauses. Appendix 10 provides some basic templates that can be easily adapted to assist in meeting and documenting the requirements of this clause and its subclauses.
8.3.2 Design and development planning	The subparagraphs of this subclause clearly articulate the requirements for design and develop planning.	
8.3.3 Design and development inputs	The subparagraphs of this subclause clearly articulate the requirements for inputs into design and development.	
8.3.4 Design and development controls	The subparagraphs of this subclause clearly articulate the requirements for controls for design and development.	
8.3.5 Design and development outputs	The subparagraphs of this subclause clearly articulate the requirements for outputs from design and development	
8.3.6 Design and Development changes	The subparagraphs of this subclause clearly articulate the requirements for design and develop changes.	
8.4 Control of externally provided processes, products and services 8.4.1 General	This clause focuses on ensuring that externally provided processes, products or services meet the QMS requirements. It places a clear requirement on the QMS to ensure that externally provided processes, products or services meet QMS requirements. It is also a requirement to determine the criteria to evaluate and select external providers and to monitor and evaluate their performance. The QMS must retain documented information as evidence of external provider evaluations.	The requirements under this clause demand a structured approach as to how they are addressed. To facilitate this, an external provider's register has been developed (see Appendix 11). In view of its comprehensive nature, the register offers an ideal opportunity to address the requirements of this clause. It is a useful exercise, and once it has been completed, ongoing maintenance will only require a simple periodic review. The register has proven to be a useful tool for highlighting the awareness and understanding of the QMS operations/activities and it also provides an excellent foundation for building a useful record of information to present as audit evidence.

Requirements	*Guidance notes*	*Hints and resources*
8.4.2 Type and extent of control	This subclause focuses on the QMS determining the type and extent of controls applied to external providers. The subparagraphs of subclause 8.4.2 clearly articulate the requirements for the type and extent of control applied.	An external providers register (see Appendix 11) can play a key role in ensuring these requirements are addressed and appropriately documented. Control mechanisms may include a check of products at delivery, site acceptance tests, supplier audits, etc. If supplier audits are required, this should be in the contracts with the suppliers. There is a section within the external providers register that focuses on controls.
8.4.3 Information for external providers	This subclause and the associated subparagraphs clearly articulate the requirements for information that the QMS is required to communicate to external providers.	The external providers register (Appendix 11) can play a key role in ensuring the requirements are addressed and appropriately documented. There is a section within the external providers register that focuses on the information that is to be communicated to the external providers. (It is located under the "external information" tab.). It would useful to give consideration to developing an SLA that clearly defines the level of service expected from the provider, in particular, aspects of the service including quality and availability.
8.5 Production and service provision 8.5.1 Control of production and service provision	Subclause 8.5.1 requires the QMS to control the manner in which products are produced and the services provided. The subparagraphs clearly articulate the requirements for control of production and service provision. It should be noted that this clause is closely linked to some other clauses (and their subclauses), including clauses 5.2, 7.1, 7.2, 7.4 and 8.2.	The information obtained in addressing the requirements of other clauses and their subclauses will provide useful input into addressing the requirements of this clause. In particular, completion of the customer records template (Appendix 6) and the external providers register (Appendix 11) will provide excellent input for addressing the requirements of this clause and evidence for audit purposes.
8.5.2 Identification and traceability	The QMS must have a process in place for the identification and traceability of outputs, to enable the demonstration of conformity to requirements. There is a requirement for the QMS to be able to identify the status of outputs in terms of the monitoring and measurement requirements at all stages of production that it has set.	The majority of organizations within the AIM community will be able to clearly demonstrate meeting the requirements of this subclause in terms of their operational products that have a set format. This is usually possible by the date and time of the dissemination of the product. In aviation, for emailed preflight briefings, a recording system will help to meet the requirements. Common practice now also includes a unique identification number/code for each product disseminated. Once a product is disseminated and archived, it should be relatively easy to trace. As a first step to addressing the requirements of this subclause, it is strongly recommended that all operational products are reviewed to ensure ease of identification and traceability. If any products are not easily identified or traced, steps should be initiated to remedy the situation. It is highly recommended that an automatic/electronic solution be found to enhance identification and traceability. This could involve the use of unique document control numbers, header and footer information or formatting of products to include unique identification numbers.
8.5.3 Property belonging to customers or external providers	This subclause focuses on the QMS responsibilities in terms of taking care of property owned by customers and or external providers.	Although this subclause is relatively straightforward, one aspect of customer and external provider property that should be taken into account is that of personal details including names, addresses and contact details.

Requirements	*Guidance notes*	*Hints and resources*
	The QMS must ensure that any customer or external provider property provided for QMS use is identified, verified, protected and safeguarded against loss or damage.	The need for confidentially in terms of this information (property) should be a high priority of a QMS. If it is not appropriately protected, steps should be taken immediately to do so – for example, via password access for authorized staff.
8.5.4 Preservation	This subclause requires the QMS to safeguard its outputs during production and service provision to ensure conformity to requirements. The note to this subclause gives examples of preservation that provide guidance for addressing the requirements.	Clear, concise and well-documented practices and procedures are of significant assistance in meeting the requirements of this subclause.
8.5.5 Post-delivery activities	This subclause and its associated subparagraphs clearly articulate the requirements for post-delivery activities.	The customer records template is a useful tool for addressing the requirements of this clause. Information on post-delivery activities could be placed under the column Products/services received, any specific requirements, controls and post-delivery activities (see Appendix 6).
8.5.6 Control of changes	The focus of this subclause is the control of changes which will ensure that products or services continue to meet their specified requirements. A key element of the clause is the authorization of changes.	Authorization of changes is inevitably a “good trail” for auditors to follow. Therefore, it is essential to have well-documented procedures applicable to the authorization and control of changes. A change is always a phase of increased risk; therefore, it is recommended to conduct a risk analysis in advance.
8.6 Release of products and services	This clause requires the QMS to have well documented practices and procedures applicable to the release of products and services. The clause also has a strong link to subclause 8.5.2.	It is essential to have well-documented practices and procedures that clearly delineate, as appropriate, the approval for the release of products.
8.7 Control of nonconforming outputs	This clause focuses on identifying any products or services that do not conform to their intended requirements. Requirements also include the establishment of controls to ensure that non-conforming products are not delivered to the customer or that their unintended use is prevented. When non-conforming products are identified, the QMS is required to take appropriate action to rectify and document the non-conformance.	Regardless of how diligent a QMS is, processes do not always go according to plan and may result in non-conforming products. The QMS should have control mechanisms in place to ensure that any non-conforming products or services are identified and rectified. The key to this clause is the manner in which non-conformities are captured and recorded. It is recommended to keep a non-conformity log or something similar, which can help to identify recurring problems. In a shift-work environment, where a number of people occupy the same position, this is a vital QMS tool to inform staff of non-conforming products. Internal problems are usually found by employees as a result of real-time analysis, reported incidents (for example, an aviation occurrence management system within a safety management system (SMS)), inspections, maintenance activities or audits, whereas external problems are identified following post-delivery verification or customer feedback. It is strongly recommended to have a procedure that describes how non-conforming products are identified and captured, how they are rectified, who is responsible for the action, what action should be taken and what records are to be kept.

Requirements	*Guidance notes*	*Hints and resources*
		Problems should not all be tackled in the same way. There may be a formal process for dealing with a major issue, but there should also be another process for tackling minor issues. The management of each work area, in close consultation with staff, should establish what is to be considered a major or minor problem, on the basis of established risk levels, and remedial actions should be defined and documented.
Clause 9 – Performance evaluation		
9.1 Monitoring, measurement, analysis and evaluation 9.1.1 General	The focus of subclause 9.1.1 is determining what it needs to monitor and measure and how it is going to carry out these activities to ensure the results obtained are valid. The associated subparagraphs clearly articulate the requirements for the monitoring, measurement, analysis and evaluation of the QMS.	The focus of subclause 9.1.1 is determining what it needs to monitor and measure and how it is going to carry out these activities to ensure the results obtained are valid. The associated subparagraphs clearly articulate the requirements for the monitoring, measurement, analysis and evaluation of the QMS.
9.1.2 Customer satisfaction	This subclause requires the QMS to put in place arrangements to monitor levels of customer satisfaction.	The fundamental goal of any organization is to satisfy its stakeholders, primarily its customers. They are arguably the very reason for an organization's existence. Satisfied customers will help to ensure that the organization receives the appropriate level of funding. Therefore, it is important to gain a clear understanding of how satisfied they are with the products or services provided. Standard ISO 9001:2015 does not specify how a QMS can gain information on customer satisfaction, but it does provide examples of how this can be achieved (see note under subclause 9.1.2). However, it requires the monitoring of information relating to customer perceptions of the organization and whether their expectations have been met. The QMS should determine the best method(s) to do this. Surveys are commonly used for this purpose, but it is essential that the right questions are asked. Whatever the QMS decides to use to assess customer satisfaction, it should be ensured that the staff is made aware of the methods chosen and that these are applied consistently.
9.1.3 Analysis and evaluation	This subclause requires the QMS to analyze and evaluate data and information, obtained either internally or externally. Subparagraphs (a)–(g) provide a clear framework of what needs to be evaluated.	It is highly desirable to present the results of the analysis and evaluation in a concise format that can be easily understood by key stakeholders. Due consideration should also be given to reviewing this as part of the QM review process input agenda discussed under clause 9.3. The objectives and KPIs established under clause 6.2 to achieve them will provide useful input into addressing this clause.
9.2 Internal audit	Subclauses 9.2.1 and 9.2.2 of this clause and their associated subparagraphs provide a clear framework for conducting internal audits.	The audit process is the "glue" that holds the QMS together. It is a primary tool that a QMS can use to ensure it is operating effectively. From an audit perspective, key aspects of the QMS are processes and procedures. It is vital that they are established in close consultation with the staff that performs the associated activity.

Requirements	*Guidance notes*	*Hints and resources*
		It is strongly recommended that the QMS selects appropriate techniques and suitable staff to perform internal audits. Unsuitable or poorly trained auditors can do significant damage to the QMS. As the QMS of an organization matures and its practices, procedures and techniques change, so should the QMS. The organization should select appropriately qualified staff that possess the personal character traits and attributes stated within ISO 19011:2011. The composition of the audit team itself is a key success factor. In general, conflict of interest should be avoided. Auditing is a way of ensuring that the QMS systems and processes are aligned and that new and improved techniques become normal practice. A good indication that a QMS is maturing is when employees welcome an internal audit of their activities. All audits should be conducted in a positive and non-threatening manner; otherwise, they will be a waste of time. Audits should help the QMS improve, and should not be conducted just to fulfil the requirements of the certification process. Standard ISO 9001:2015 does not specify the techniques to be used for conducting an internal audit. Unlike certification audits, internal audits are less formal and should be scheduled according to the QMS demands, priorities, available resources and risks associated with operations. To facilitate the internal audit process, it should be documented as guidance for all staff. The internal audit does not assess all facets of the QMS at once, but uses samples of job descriptions, procedures, instructions, contracts (SLAs), policies, plans, organization charts, flow charts, etc., including the linkages among these documents. A flexible audit schedule is a critical component of the audit process, and should be developed prior to planning and budgeting activities. For example, 1–2 months prior to the development of the annual operational plan, the QMS should ensure that any significant issues identified during the audit are addressed as part of the planning process. The same applies to the budgeting process. Outcomes of an audit can highlight areas that require an injection of funds to rectify a specific issue. Internal audits should also be planned and carried out prior to external audits. However, they should not be performed only a few weeks before an external audit just to provide evidence to an auditor. They should be part of the day-to-day activities of the QMS.
9.3 Management Review	Subclause 9.3.1 requires reviews of the QMS to be conducted by top management at planned intervals to ensure ongoing suitability and effectiveness.	Top management involvement in quality management review meetings (QMRMs) – preferably as chairperson – is fundamental to the success of the QMS. Therefore, it is imperative that top management is engaged early in the development and implementation of a QMS.

Requirements	*Guidance notes*	*Hints and resources*
9.3.1. General		
9.3.2 Management review inputs	This subclause and its subparagraphs provide a clear framework for what must be considered at a QMRM.	The subparagraphs of subclause 9.3.2 provide a standing agenda framework for QMRMs that should be adapted to meet the QMS. It provides the QMS with structured evidence and helps to analyze and generate relevant input for management review.
9.3.3 Management review outputs	This subclause provides specific outputs from management reviews.	It is highly recommended that the QMRM agenda is formulated to ensure the required outputs can be achieved.
Clause 10 – Improvement		
10.1 General	This clause has a clear focus on improvement underpinned by meeting customer needs and enhancing customer satisfaction.	Communicating with QMS customers is a crucial strategy in meeting the requirements of the clause. A key resource for this purpose is the customer records template (see Appendix 6), which can provide useful input into meeting the requirements of this clause.
10.2 Nonconformity and corrective action	This clause states the requirements for the occurrence of a non-conformity. The requirements also include action to prevent a similar non-conformity occurring. This is achieved via review and analysis to determine what caused it, and any actions to prevent it re-occurring in the future.	There is a clear link between clauses 8.7 and 10.2, and a methodology for meeting the requirements of this clause has to be put in place. This clause requires that appropriate action be taken to address the effects of the problem. This may require a simple correction by the duty officer or, in a major event, significant levels of resources. A risk analysis can help to determine the appropriate actions that need to be taken. Any ongoing risks should be recorded in the risk register and considered during future planning activities. Any non-conformities and subsequent actions to prevent the reoccurrence and the effectiveness of the corrective action(s), should be duly documented and retained. Therefore, due consideration should be given to the development of a non-conformities log or similar document.
10.3 Continual improvement	This clause requires the QMS to work continually to improve and specifically use the outputs from analysis and evaluation (see subclause 9.1.3) and from the management review process (see subclause 9.3.3).	This clause aims to ensure progress is being made to improve the effectiveness of the QMS. It raises questions such as: Are outputs better this year than last year? Is the use of resources being optimized? Is better use being made of system indicators such as audits, management review and data analysis? Overall, it is important that the QMS processes have identified any issues and that they have been documented and are in the process of being rectified – this is what happens every day in organizations around the world.

CHAPTER 3. STEPS FOR IMPLEMENTING QMS

3.1 Implementation overview

3.1.1 Tables 2, 3 and 4 provide an overview of the steps that need to be taken to develop and implement a QMS. They can be used to provide a foundation tool at an initial meeting to discuss adoption of a QM approach to the delivery of products and services.

3.1.2 It is not possible to determine exactly how long it takes to implement a QMS, nor achieve certification of compliance with ISO 9001. Many factors can affect the time required to implement a QMS, including: the size of the organization, the extent to which the QMS will be introduced within the organization, whether QMS implementation is assisted by a consultant, the maturity of the QMS processes and documentation, the availability of resources, and the commitment of top management and staff.

3.1.3 Experience suggests that, with due regard to the above factors, 18–24 months is a realistic and achievable time frame for a small QMS or for specific sections of a large QMS. Small sections or units (approximately 20 staff) in a QMS could implement and achieve certification of compliance with ISO 9001 within a minimum of 18 months. That time period should also provide the opportunity to accumulate a body of evidence that clearly demonstrates, at audit, the successful implementation of the QMS.

3.1.4 It may also be advisable to adopt an incremental approach where a QMS is developed and implemented for different sections or programme areas. Success in these individual or smaller areas has the real potential to raise the confidence and level of staff buy-in, as well as making the task more manageable for the QM team overseeing the QMS implementation process.

Table 2. Primary steps and broad timeline for the first 6 months of development and implementation of a QMS to achieve certification of compliance to ISO 9001:2015

QMS development and implementation activities	*Month 1*	*Month 2*	*Month 3*	*Month 4*	*Month 5*	*Month 6*
Step 1 Gain formal commitment and endorsement of top leadership/management						
Step 2 Select a professional quality manager						
Step 3 Select a recognized training provider						
Step 4 Provide introductory QM training						
Step 5 Conduct a gap analysis						
Step 6 Conduct an initial QMRM. [This establishes the importance of the role of the QMRMs. It is appreciated that all aspects of the QMRM agenda will not be addressed at this early stage.]						
Step 7 Commence work on rectifying identified gaps						
Step 8 Identify processes and develop procedures						
Step 9 Establish levels of customer satisfaction and tools to acquire and measure this information						
Step 10 Identify and train appropriate staff to undertake the role of internal auditor						

Table 3. Primary steps and broad timeline for the second 6 months of development and implementation of a QMS to achieve certification of compliance to ISO 9001:2015

QMS development and implementation activities	*Month 7*	*Month 8*	*Month 9*	*Month 10*	*Month 11*	*Month 12*
Step 11 Conduct a first internal audit						
Step 12 Conduct a QMRM						
Step 13 Select a third-party organization to perform the ISO 9001:2015 certification of compliance						
Step 14 Conduct a second internal audit						
Step 15 Conduct a QMRM						
Step 16 Conduct a third internal audit, if required						

Table 4. Primary steps and broad timeline for the third 6 months of development and implementation of a QMS to achieve certification of compliance to ISO 9001:2015

QMS development and implementation activities	*Month 13*	*Month 14*	*Month 15*	*Month 16*	*Month 17*	*Month 18*
Step 17 Conduct a QMRM						
Step 18 Prepare for the external audit						
Step 19 Conduct a third-party certification audit (stages 1 and 2)						
Step 20 Celebrate certification of compliance						

3.2 Step 1 – Obtain formal endorsement of top management

3.2.1 Clause 5.1 of ISO 9001:2015 emphasizes the need for demonstrated commitment from top management. In fact, it is a critical first step in the development and implementation of a QMS. The demonstration of commitment should involve formal endorsement, communicated to all staff.

3.2.2 Top management must ensure that the finances to support the QMS will be available. The proposed development and implementation of the QMS should be formally documented and include the proposed implementation strategy, a broad timeline and an estimated budget. It is strongly suggested that the early development and implementation stages of the QMS be within a project framework.

3.2.3 It is not possible within the context of this Guide to indicate the exact cost of implementing a QMS. The scope of the QMS and the costs of training, consultancies and certification bodies will differ significantly across the AIM community. However, this Guide points to some important questions concerning the financial commitment required. Although the answers to these questions will enable the development of a reasonably accurate budget, it would also be advisable to set up a contingency fund to cover indirect costs that may not have been identified initially. For example, it may be decided to digitalize AIM activities in order to improve the quality of products and services.

3.2.4 A word of caution regarding this step: unless the formal endorsement and commitment of top management can be obtained, and the appropriate level of resources secured, attempting to implement a QMS could be a waste of time and resources. The failure of this process will have a significant and adverse impact on staff.

3.3 Step 2 – Select a professional quality manager

3.3.1 The appointment of a professional quality manager is a key factor to the success of a QMS. It is strongly recommended that a full-time staff member be appointed at a senior level, and it is beneficial for the implementation process if the officer has a knowledge of the business.

3.3.2 The position will inevitably be the driving force behind the QMS and the primary focus for issues pertaining to the QMS. It requires an individual with a specific set of skills, knowledge and character traits that will earn him/her the trust of top management and direct access to it. See the guidelines for auditing management systems in ISO 19011:2018.

3.3.3 It is essential that the individual appointed has a strong desire for, and interest in,

undertaking the challenges associated with developing and implementing a QMS. A forced or political appointment will potentially, if not inevitably, undermine the QMS and result in its failure.

3.4 Step 3 – Select a recognized training provider

3.4.1 It is strongly recommended that several potential training providers be interviewed, to ascertain their knowledge and relevant experience, and how well they would align with the culture of the organization. The interview process provides an opportunity to assess their commitment to working with the organization. The level of interest they have shown prior to the interview in obtaining information about the activities of the organization and the products and services it provides should be ascertained.

3.4.2 The credentials of any potential training providers should be carefully assessed by checking their qualifications and course content. It is important that they are accredited trainers and can provide an introductory course that will "demystify" ISO 9001 for all staff involved in the QMS.

3.4.3 The ICAO community has AIM Organizations with whom it may be useful to form a mentor/twinning partnership. The benefits include acquiring skills and knowledge from other Aviation industry Member with mature QMSs as well as providing an opportunity to ask questions about QMSs.

3.5 Step 4 – Provide introductory quality management training

3.5.1 An introductory training session for all staff involved in the QMS should be organized, starting with the core QM team including the Chief Executive Officer/Director. A basic introductory ISO training course helps to ensure the successful implementation of a QMS by providing sound understanding of the principles and practices pertaining to ISO 9001. Ideally, this course should be provided by a registered training organization with expertise in this area. Although not ideal, if a staff member has to conduct the training session, he/she must have a sound and demonstrated background in the subject matter combined with, wherever possible, formal training skills.

3.6 Step 5 – Conduct a gap analysis

3.6.1 A gap analysis is a technique for determining the steps to be taken to move from the current state to a desired future state. In the case of QMSs, a gap analysis is undertaken to clearly identify which clauses of ISO 9001 are currently not being fully addressed (or not addressed at all) and to develop remedial actions. The gap analysis should be conducted by members of the QM team/section who have formal auditing qualifications. Gap analyses can be conducted with small groups of staff. For example, a gap analysis can be conducted with the senior management group and a separate

gap analysis with middle management and/or operational staff. It is not unusual to receive different responses to questions depending on the position and level of staff within the organization.

3.6.2 The two gap analysis tools (part A and part B) listed below provide a structured framework to assess the current status of a QMS in terms of fulfilling the ISO 9001 clauses:

a. Part A, Gap analysis, is aligned with the clauses of ISO 9001. The gap analysis template in Appendix 12 provides comments and notes to assist users.
b. Part B, Gap analysis findings, lists the findings and remedial actions that are required to close the identified gaps between ISO 9001 and the current management system of an organization (see Appendix 13).

3.6.3 An important consideration in using the gap analysis tools is that, for most staff, this will be an introduction to an audit-like process and the practical aspects of a QMS. It is therefore important that it is a positive experience from all perspectives. Any gap analysis or audit should be focused on the processes and the overall system, not the individuals following the practices and procedures provided.

3.7 Steps 6, 12, 15 and 17 – Conduct quality management review meetings at these steps

3.7.1 There are no specified time periods applicable to conducting quality management review meetings (QMRMs). However, they are essential during the initial development and implementation stages of the QMS and should be conducted on an as-required basis.

3.7.2 There is merit in conducting QMRMs following internal and external audits, to review the findings and plan for follow-up/corrective actions. Some organizations may also find it beneficial to conduct a QMRM prior to an external surveillance or certification audit, in order to identify gaps that can be filled prior to the external audit(s) being conducted.

3.7.3 Clause 9.3 of ISO 9001:2015 provides detailed specifications (inputs) for management reviews (QMRMs).

3.7.4 As per previous comments in Chapter 2 of this Guide, under clause 5.1 of ISO 9001:2015, it is important that a member of top management chairs QMRMs. The meetings provide useful insight into the basic processes and enable management to respond accordingly. It is imperative that the management fully understand and appreciate the requirements under clause 9.3 and subclauses 9.3.2 and 9.3.3 of ISO 9001:2015. The secretarial duties should nominally be undertaken by the quality manager/section.

3.7.5 Attendees at QMRMs should include senior officers and other staff within the scope of the QMS, as appropriate, and the internal auditor(s) should also attend. As mentioned previously, a definition of top management" is provided in ISO 9000:2015.

3.8 Step 7 – Commence work on rectifying identified gaps

3.8.1 The outcomes of step 5 (gap analysis) and actions resulting from step 6 (QMRMs) will provide a priority for rectifying identified gaps.

3.8.2 It is important to monitor progress and to document the actions and results that will need to be considered at the next QMRM.

3.9 Step 8 – Identify processes and develop procedures

3.9.1 Developing and writing processes and procedures that are currently being followed is a critical component of a QMS. It is imperative that they are developed in close consultation with the staff who follow them as part of their duties. There may be merit in providing specific QMS staff with training in how to write procedures.

3.9.2 It is important to find a balance between overdocumenting and not providing sufficient information, while ensuring that processes and procedures are clearly articulated and unambiguous. Finding the right balance usually comes through experience, including learning from others who have been through the same or a similar process.

3.9.3 A process matrix (Appendix 3) is a key outcome of this step.

3.9.4 At the commencement of implementation, it is important to develop specific, measurable, attainable, relevant, timely and, where possible, automated key performance indicators (KPIs) that reflect the actual activities of the QMS.

3.10 Step 9 – Measure customer satisfaction

3.10.1 It is essential that appropriate client satisfaction measuring tools are established from the outset, so as to provide a baseline from which to assess improvement in service delivery. Standard ISO 9001 notes that there are several ways in which the level of client satisfaction can be measured.

3.10.2 Industry focus groups can be used as viable measuring tools where the organization communicates face to face with representatives of a particular industrial sector that it serves.
Focus groups are also useful because they provide an opportunity to ask questions,

clarify customer feedback and expectations, and develop strategies with the customer to rectify any problems. They can also help to establish a core reference group that will gain better knowledge and understanding of the environment in which the organization operates – this will add useful input for addressing clauses 4.1 and 4.2. It is important that the actions arising from these meetings and the levels of customer satisfaction thereby identified are fully documented and agreed by all the parties concerned. The (agreed) documented outcomes will enable the identification of trends in customer satisfaction over a specific period of time.

3.10.3 Customer survey tools can enable the QMS to reach a larger audience. However, it is notoriously difficult to get customers to respond to surveys. It takes a great deal of tenacity and patience to obtain a sufficient number of responses that will provide credible and meaningful feedback on customer satisfaction. When preparing a customer satisfaction survey, the following key points should be considered:

a. The reason for conducting the survey, its target group and the most appropriate time to conduct it should be clearly established;
b. The contents of the survey should be well organized;
c. A budget for the survey should be prepared;
d. The questionnaire should be well designed and the questions clearly formulated;
e. The method that will be used for the survey (email, web, hard copy, telephone, focus group, etc.) should be clearly defined;
f. The method for analyzing the results should be clearly established;
g. The questionnaire should be pre-tested before finalization;
h. Dates for dispatching and returning the questionnaire should be set;
i. The survey should be conducted on a scheduled basis to provide continuity of feedback and trends in the data;
j. Those conducting the survey should display tenacity and patience when collecting the questionnaires;
k. The data analysis process should be clearly defined and implemented;
l. Due care should be taken in interpreting and evaluating findings;
m. Special attention should be paid to developing the actions needed to address the issues raised (root cause analysis);
n. A survey report should be disseminated to key stakeholders and, most importantly, the QMS staff.

3.10.4 A customer feedback mechanism on the QMS web page can also be a useful tool.

3.11 Step 10 – Identify and train staff to undertake the role of internal auditor

3.11.1 It is critical that due care be taken in selecting staff to perform the role of internal auditor. Individuals who show potential as auditors should be given formal training

by a registered training organization.

3.11.2 It is imperative that the required level of competence of all internal auditors is maintained via refresher training or, more importantly, active participation in the audit programme.

3.11.3 Apart from having the appropriate training, selected staff should also possess the necessary personal qualities and attributes that enable them to act in accordance with the principles of auditing. Standard ISO 19011:2011 lists six principles of auditing:

a. **Integrity**: the foundation of professionalism
Auditors should perform their work with honesty, diligence and responsibility, observe the law and make the disclosures required by law and the profession.

b. **Fair presentation**: the obligation to report truthfully and accurately
Audit findings, conclusions and reports should reflect truthfully and accurately the audit activities. Significant obstacles encountered during the audit and unresolved diverging opinions between the audit team and the individual being audited should be reported.

c. **Due professional care**: the application of diligence and judgement in auditing
Auditors should exercise care in accordance with the importance of the task they perform and the trust placed in them by audit clients and other interested parties. Having the necessary competence is an important factor.

d. **Confidentiality**: integrity and security of information
Auditors should be prudent in the use and protection of the information acquired in the course of their duties. Auditors should not disclose information without appropriate authority unless there is a legal or professional obligation to do so.

e. **Independence**: the basis for the impartiality of the audit and objectivity of the audit conclusions
Auditors should be independent of the activity being audited and should be free from bias and conflict of interest, wherever practical. Auditors should maintain an objective state of mind throughout the audit process to ensure that the audit findings and conclusions are based only on evidence.

f. **Evidence-based approach**: the rational method for reaching reliable and reproducible audit conclusions in a systematic audit process
Audit evidence should be verifiable. It will be based on samples of the information available, as an audit is conducted during a finite period of time and with finite resources. The appropriate use of samplings is closely related to

the confidence that can be placed in the audit conclusions.

3.11.4 It is suggested that organizations obtain a copy of ISO 19011:2018, which provides excellent guidelines on auditing. A copy may be purchased from the ISO online store (https://www. iso. org/store. html).

3.12 Steps 11, 14 and 16 – Conduct internal audits

3.12.1 Conducting an audit and developing a robust internal audit schedule is a critical component of a QMS.

3.12.2 It is strongly recommended that an organization's internal auditors widely publish an audit schedule, as it will provide a useful planning tool for key stakeholders.

3.12.3 The internal audit process should cover all facets of preparing for and conducting audits based on a sound audit programme: audit scope, audit criteria, references, definitions, audit schedule, audit performance, follow-up audits, corrective action, audit documentation, audit failure and management review.

3.12.4 Paragraph 3.11.3 above addressed the qualities required of auditors. However, it is also important to note that auditors must be objective and impartial and shall not audit their own work. This situation can be relatively easily achieved within a QMS internal audit environment.

The quality manager should ensure that internal audits are conducted by staff who do not work in the area being audited. It should be noted that the exchange of internal auditors among different organizations can be a useful process. The exchange of auditors, where possible, can also be used to enhance the value of the audit and the individual auditor's competencies.

3.13 Step 13 – Select a certification body to conduct the certification audit

3.13.1 In the case of the certification body (third party or external auditor), the need for objectivity and impartiality is even more important. There are many organizations globally offering consulting services to assist in the development and implementation of a QMS.

3.13.2 It is important to note there are some organizations that, in addition to their consulting services, may also offer their services as the third-party certification body. This is totally inappropriate and removes the impartiality and objectivity from the process and will create a potential conflict of interest. Any organization contemplating engaging a conformity assessment body should give it considerable thought, as the credibility of the QMS and its certification of compliance with ISO 9001 is underpinned by the independence of the third-party external audit

process. See paragraph 3.11.3 of this Guide and ISO 19011:2018, in particular, subparagraph (e).

3.13.3 When selecting a certification organization, the QMS should consider the following:

a. Whether it complies with standard ISO/IEC 17021:2011, Conformity Assessment – Requirements for Bodies Providing Audit and Certification of Management Systems (ISO/IEC, 2011), and whether it can demonstrate a positive track record;
b. Whether its profile and standard mark are credible from both national and international perspectives;
c. Whether it currently provides certification for organizations providing similar products and services;
d. Whether it can commit to providing strict and thorough audits and whether an auditor is available with a sound understanding and appreciation of the activities, products and services of the organization;
e. Whether it has a definitive fee structure for the three-year certification period including any costs associated with travel;
f. Whether it can obtain testimonials from current and former clients as to the quality of its services.

3.13.4 To ascertain further credentials pertaining to potential certification bodies, it is highly recommended to consult the website of the relevant national accreditation organization. This will provide a list of national certification bodies, and access can be obtained through the International Accreditation Forum website (www.iaf. nu). Additional information on selecting a certification body may be accessed through ISO web page: https://www.iso.org/iso/home/standards/certification.htm.

3.14 Steps 18 and 19 – Prepare for and perform an external audit

3.14.1 Preparing for an ISO 9001 third-party certification audit can be a daunting experience for all concerned. However, the following are some guidelines for this process:

a. The organization should embrace the audit process as a positive experience, which will help to improve its processes, systems and overall quality of its products and services.
b. The organization should liaise with the certification body to establish dates for the audit that suit all concerned. Most importantly, the organization should not consider undergoing the certification audit unless there is a strong indication – based on the success of internal audits – that it will be successful. It may be useful to undergo a pre-audit provided by the certification body if funding allows.
c. All staff should be provided with adequate lead time to prepare for the audit.

The proposed 5-month period for preparation for external audit (see Table 4) is a nominal period. The actual development and implementation of the QMS throughout the proposed 18-month minimum period should ensure a significant amount of the pre-external audit preparation has been done – if not, the implementation has not been undertaken correctly.

d. If there is a lack of confidence in the ability of the QMS to successfully undergo an external third-party audit, then it should be delayed until such time it is ready. To do otherwise would be setting up the QMS for failure, which is unacceptable.
e. The certification auditors should be briefed on any potential safety issues concerning the location they will visit.
f. All documentation that may be needed during the audit should be easily accessible (including reports of previous internal audits and QMRMs).
g. A culture should be developed within the QMS that encourages staff not to attempt to hide or cover up any known problem areas.
h. It should be noted that an audit finding of minor non-conformances is not a negative. In fact, it shows that the audit process is working by providing a mechanism for identifying potential risks to the QMS.

3.15 Step 20 – Celebrate certification of compliance

3.15.1 It is imperative that the achievement of certification of compliance to ISO 9001:2015 is appropriately recognized by top management and celebrated by all staff. In fact, it is a reward and recognition of the high standard of products and services they provide.

3.15.2 However, it must be remembered that certification of compliance is not the end of the QM journey, although it is a milestone. The findings of the external audit need to be reviewed at a QMRM, and the appropriate actions taken to address any remedial actions.

3.15.3 Importantly, the certification of compliance provides an excellent baseline on which to measure ongoing improvement of the organization.

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APPENDIX 1. ENVIRONMENTAL SCANNING TOOL

Environmental scanning tool (SWOT analysis)	
Scan scope (quality management system)	
Date of scan	
Scan participants	

Notes

1. *This template has been developed to assist in meeting the requirements of clause 4.1 of standard ISO 9001:2015, Quality Management System – Requirements.*
2. *The scan is underpinned by the traditional SWOT analysis methodology, which provides a proven and useful tool for identifying and analyzing the strengths, weaknesses, opportunities and threats applicable to the environment in which the organization operates. Only those issues that are relevant to the organization's purpose and strategic direction and that affect, or have the potential to affect, its ability to achieve its intended outcomes should be considered.*
3. *The scan should be conducted at a minimum of once a year and ideally just prior to commencing the annual planning process.*
4. *A SWOT analysis is a process that can be used to identify an organization's strengths, weaknesses, opportunities and threats. This is discussed further below.*
5. *The external context considers issues from the following local, regional, national and international perspectives: legal, technological, competitive, market, cultural, social and economic.*
6. *The internal context considers the values, culture, knowledge and performance of the organization.*

Step 1 – Strengths, weaknesses, opportunities and threats analysis

A SWOT analysis is a process that can be used to identify an organization's strengths, weaknesses, opportunities and threats.

Strengths are characteristics of the organization that allow operation more efficiently and effectively than competitors. Consider:

- What does the organization do well?
- What advantages does the business have over other internal sections or external organizations, including competitors?
- What makes the organization different from competitors?

Weaknesses are areas that are recognized as needing improvement. Consider:

- What can be done better?
- What causes problems or complaints (information from root cause analysis)?
- Which capabilities need modifying, strengthening or divesting for the future?
-

Opportunities are trends, circumstances or business opportunities that may be taken advantage of. Consider:

- What are the changes in technology or markets?
- What local and global events may be useful?
- What are the changes in customer/societal values?

Threats can be external or internal and are anything that can adversely affect business or operations. External threats could be economic, new legislation or even a new competitor in the market. Internal threats could be a skill or staff shortage within the organization. Consider:

- What obstacles are there for ongoing operation?
- Are there any potential competitors to the business?

Step 2 – Categorize from the following national, international, regional and local perspectives

Legal:

- Possible changes in regulation/legislation
- Impacts of these changes on business
- Stability of government
- Outsourcing regulations
- Government bureaucracy – rules and regulations
- Legal constraints

Technological:

- Maturation of existing technologies
- Technological developments or trends that affect or could affect the business
- New product development and potential markets: government, international, resource sector, etc.
- Productivity improvements through automation
- Telecommunication infrastructure
- Online connectivity and digital data

Competitive:

- Competitors
- Differences from competitors
- Competitiveness of the organization and what affects its ability to compete
- Customer problems and complaints with current products and services

Market:

- General market conditions that affect the business
- Market direction
- Needs for the organization's products and services in the market
- Customer market technology opportunities

Cultural/social:

- Current or emerging trends in lifestyle
- Implications of these trends
- Demographic trends that may affect market size (growth rate, income, population

shifts)
- Whether these trends represent an opportunity or a threat
- Changes in consumer behavior
- Increasing environmental awareness
- Urbanization
- Consumer demands; personalization and high-end experiences
- Public demand for transparency and participation in decision-making

Economic:
- National and internal financial trends (trends in economic forces)
- Economic trends that may have an impact on business activity
- Emerging markets
- Economic factors: inflation, employment levels, supply, energy available or the global financial situation

Step 3 – Prioritize

Once the SWOT analysis is completed, use a prioritization process to identify the top four or five items in each section. Consider:
- What must be addressed immediately?
- What can be handled now?
- What needs researching further?

Develop and document:
- Realistic strategies to address each item
- Resources required – human and costs, if known

Steps 1 and 2 – Analyse and categorize
(use one line per item)

International, national, regional and local				
Perspective	Strengths	Weaknesses	Opportunities	Threats
Legal	1. 2. 3. 4.			
Technological	1. 2. 3. 4.			
Competitive	1. 2. 3. 4.			
Market	1. 2. 3. 4.			
Cultural/social	1. 2. 3. 4.			
Economic	1. 2. 3. 4.			

Step 3 – Prioritize

Priority	*Strengths*	*Weaknesses*	*Opportunties*	*Threats*	*Integrated in planning process (Y/N)*
	Priority 1:	Priority 1:	Priority 1:	Priority 1:	
	Strategy:	Strategy:	Strategy:	Strategy:	
	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	
	Priority 2:	Priority 2:	Priority 2:	Priority 2:	
	Strategy:	Strategy:	Strategy:	Strategy:	
	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	
	Priority 3:	Priority 3:	Priority 3:	Priority 3:	
	Strategy:	Strategy:	Strategy:	Strategy:	
	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	
	Priority 4:	Priority 4:	Priority 4:	Priority 4:	
	Strategy:	Strategy:	Strategy:	Strategy:	
	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	
	Priority 5:	Priority 5:	Priority 5:	Priority 5:	
	Strategy:	Strategy:	Strategy:	Strategy:	
	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	

APPENDIX 2. STAKEHOLDER ANALYSIS TEMPLATE

Stakeholder/interested party name	*Community sector/industry*	*Relationship/requirements/ interaction with the organization*	*Comments (if applicable)*

APPENDIX 3. PROCESS MATRIX

Objectives				*Key performance indicators*			
[Insert QMS objectives here]				[Insert KPIs associated with QMS objectives here]			
Core process	*Purpose*	*Inputs*	*Outputs*	*Process owner*	*Process risks*	*Controls/resources*	*Monitors/measures*
1. [Insert identified core process here]	[Provide a detailed description of the process purpose]	[Detail the inputs and dependencies for the process here]	[Detail the outputs (products and services) of the process here]	[Officer responsible for the process]	[Detail the identified risks associated with the process]	[Provide details of any controls applicable to the process and specific resources that are required for the process]	[Detail any monitors and measures applicable to the process]
2.							
3.							
4.							

APPENDIX 4. QUALITY POLICY

"QMS name" [insert name here]

Quality policy [sample only]

The "*QMS name*" is committed to ensuring the provision of high-quality products and services to enhance the safety and economy of operations within the region of responsibility.

"*Organization name*" is focused on improving the quality, consistency and utility of the service in line with the identified needs of key stakeholders by fostering innovation and continual improvement through the ongoing review of quantitative and qualitative measures of performance.

This policy will be underpinned and sustained by practical application of the seven principles of quality management and compliance with national and international regulatory requirements.

_____

"*QMS*"/Organization Director

Date __ /__ / __

APPENDIX 5. AUDIT QUESTIONS FOR TOP MANAGEMENT

	Reference clause in ISO 9001:2015
Leadership and commitment	
A. Context of the organization	
What are the internal and external issues that affect your organization?	4.1
Has the quality management system (QMS) identified and addressed these issues as part of the planning process?	4.1
What changes (if any) are currently affecting the QMS?	4.1
Have the statutory and regulatory requirements that affect the QMS been defined?	4.2
B. Leadership and commitment for the QMS	5.1.1
How do you demonstrate accountability for the effectiveness of the QMS?	5.1.1.a
How do you ensure that the QMS quality policy and quality objectives are established and aligned with the strategic direction of the organization?	5.1.1.b
What role do you play in ensuring that the QMS has the necessary resources for operation?	5.1.1.e
What role do you play in communicating the importance of conforming to the requirements of the QMS?	5.1.1.f
What role do you play in ensuring that the QMS meets its objectives?	5.1.1.g
What role do you play in directing and supporting staff to contribute positively to the QMS?	5.1.1.h
How do you promote continual improvement within the QMS?	5.1.1.i
What role do you play in supporting other managers within the QMS to demonstrate leadership in their area of responsibility?	5.1.1.j
C. Process approach	
What is your understanding of the process approach and how is it promoted within the organization?	5.1.1.d
How is the QMS integrated within the organization's business processes?	5.1.1.d
Has the organization established and implemented the processes needed for the QMS?	5.1.1.d
Has the organization determined the inputs and outputs expected from these processes?	4.4.1.a
Has the organization determined the sequence and interaction of these processes?	4.4.1.b
Has the organization assigned the responsibilities and authorities for these processes?	4.4.1.e
How does the QMS evaluate these processes and implement any changes that are needed to ensure the processes achieve their intended results?	4.4.1.g
D. Risk-based thinking	
What role do you play to ensure any risks and opportunities identified as possibly affecting the organization's ability to achieve products or services conform and meet customer requirements?	5.1.1.b
How are risks within the QMS identified and managed? How are they escalated?	6.1.1
How are potential risks that affect the QMS addressed and monitored?	6.1.1
E. Customer focus	5.1.2
What role do you play in ensuring that customer requirements are determined, understood and met?	5.1.2.a
What mechanisms are in place to ensure that applicable statutory and regulatory requirements are determined, understood and met?	5.1.2.a
How do you ensure that the focus on the consistent provision of products and services is maintained throughout the organization?	5.1.2.a
How do you ensure that the QMS maintains its focus on enhancing customer satisfaction?	5.1.2.c
F. Quality policy	5.2
What role do you have in establishing the QMS quality policy?	5.2.1
How does the quality policy reflect the purpose and context of your organization and how was this determined?	5.2.1.a
Was the quality policy utilized when formulating the QMS quality objectives?	5.2.1.b

	Reference clause in ISO 9001:2015
How does the quality policy account for the organization's commitment to satisfy requirements? Does the quality policy commit to the organization's continual improvement? How is the quality policy communicated throughout the organization? Is it available as documented information?	5.2.1.c 5.2.1.d 5.2.2.a/5.2.2.b
G. Organizational roles, responsibilities and authorities	5.3
Are roles, responsibilities and authorities defined within the QMS? Is each role clearly assigned, communicated and understood within the organization? Does each employee have an up-to-date job description and duty statement? Are duty statements reviewed on a scheduled basis to ensure they are current? Which role is responsible for reporting on the performance of the QMS to top management?	5.3 5.3 5.3 5.3 5.3
H. Management review	
What role do you have in quality management reviews? How often are these reviews carried out? Who is involved in the management reviews? How is the information presented? What outputs are derived from these management reviews? What documented information is retained as evidence of the results of management reviews and where is this information available?	9.3 9.3.2 9.3.2 9.3.2 9.3.3 9.3.3

APPENDIX 6. CUSTOMER RECORD TEMPLATE

Customer name and location of operations	Products/services received			Review of customer requirements		Method of review	Service level agreement or contract details (number, validity, place of storage, etc.)	Comments including perceived and known level of customer satisfaction and the potential impact of products/services on customer operations
	Specific requirements	Controls	Controls	Review period: 12/18/24 months or other	Last review date			

_____

APPENDIX 7. QMS DUTY STATEMENT

"QMS" duty statements – duties pertaining to ISO 9001

The following are suggested duties that could be included in staff duty statements at the appropriate level. The suggested top management statement demonstrates its strong commitment to the quality management system (QMS).

Level: Top management – Chief Executive Officers, Directors, Deputy Directors
Lead activities to ensure the quality and effectiveness of the QMS and [as appropriate] the ongoing development, implementation and maintenance of the QMS to achieve and maintain certification of compliance with ISO 9001:2015
Level: Section heads
Plan and develop strategies for the quality and effectiveness of the QMS products and services and [as appropriate] the ongoing development, implementation and maintenance of the QMS to achieve and maintain certification of compliance with ISO 9001:2015
Level: Operational managers
Manage the implementation of strategies for the quality and effectiveness of the QMS products and services and [as appropriate] the ongoing development, implementation and maintenance of the QMS to achieve and maintain certification of compliance with ISO 9001:2015
Level: All other levels
Participate in ensuring the quality and effectiveness of the QMS products and services and [as appropriate] the ongoing development, implementation and maintenance of the QMS to achieve and maintain certification of compliance with ISO 9001:2015

APPENDIX 8. COMPETENCES NEEDS ANALYSIS

Competence needs analysis

Conducted by: .....

Date: __ / __ / __

Employee name:				*Position title/number:*					
Duties (see duty statement)	*Competence required*	*Competence*		*Type of training required*	*Title of competence framework if one already exists*	*Proposed training provider*	*Where are records retained?*	*Validity period*	*Date achieved*
		Yes	*No*						

APPENDIX 9. COMMUNICATION PLAN

Communications method	*Target audience*	*Date*	*Responsibility*
[How will you get your messages out?]	[Who are you trying to reach with this method?]	[When should it happen?]	[Whose job is it?]
External			
Internal			

APPENDIX 10. PROJECT TEMPLATE

Title project
Overview

1. Project definition				
Project title				
Programme				
Start date / end date				
Stakeholders	[List the key stakeholders or stakeholder groups who will be affected by the initiative. Stakeholders provide or receive a service to or from the project. They are critical to the success of the project.]			
Related projects	[List any related projects that are dependent on this initiative, or projects that are interdependent on this initiative or projects upon which this initiative is dependent. These may share data, function, technology or staff with the project.]			
Project authority	[Detail the lines of authority and responsibility]			
Project funding	[Identify the source(s) of funding]			
Project team	*Name*	*Position/section*	*Phone*	*Email*
Project sponsor				
Project manager				
2. Project description				
National objective	[Include overall QMS objective]			
Project objectives	[List the objectives of the project. Objectives need to be specific (addressing client requirements) and measurable]			
Background	[Introduction or background to the project including, where appropriate, identified client requirements]			
Project description	[Provide a concise description of the project]			
Scope	[Identify the broad boundaries of the project and what the project is designed to achieve, with a specific focus on any customer requirements. It is also useful to consider what may be outside the scope of the project.]			
Deliverables	[What are the project deliverables?]			
3. Justification				
Expertise	[Provide a description of the expertise necessary to undertake the project]			
Benefits	[Provide an explanation as to why this initiative has been identified as a priority and associated desired benefits/outcomes. Include links to QMS objectives, priorities, strategic plans and meeting identified client needs.]			
Impact	[What are the consequences if the project is not undertaken?]			
4. Communication strategies				
Description	*Target audience*	*Delivery method*	*Frequency*	*Responsibility*

[Notes: How are details of the project going to be communicated to the stakeholders, in particular key customers? Include meetings, liaison and progress reports. Progress reports should occur at agreed predetermined time intervals or at key milestones. They should include the actual progress against the planned schedule (including cost, time and performance).]

5. Evaluation methods			
Description	*Methodology*	*Target*	*Responsibility*

[Note: Clearly define the KPIs that will indicate that the initiative has been successfully completed.]

6. Milestones				
Milestone	*Accountability*	*Dates*	*Status*	
1				
2				
3				
4				
5				
6				
7. Risk summary				
Risk description	*Likelihood*	*Impact*	*Risk*	
8. Budget				
Description	*2017–2018*	*2018–2019*	*2019–2020*	*Ongoing*
Overheads				
Total				

Title project
Statement of requirements

Version control

Version	*Author*	*Date*	*Comments*

Version acceptance

Approver	*Signature*	*Date*	*Comments*

Note: Approval of this statement of requirements indicates an understanding and formal agreement that the product and/or service should be developed and implemented in accordance with these requirements.

Title project
Statement of requirements

Purpose

[1. State the purpose of the project. This is a brief statement of what the project is and what it covers. Flow diagrams can be useful to illustrate the system (or part thereof) that the project covers.

Note that the purpose of the statement of requirements is to specify the services and user requirements that need to be satisfied and achieved for the project to meet its objectives. References supporting the requirements should be provided.

As required, this document will be used as a reference for technical specifications, training documentation, and the development of user and acceptance testing criteria. Therefore, it can be useful to assign reference numbers and priorities to each requirement for tracking and subsequent evaluation.]

Background

[2. Who has requested this project? What are the driving issues related to this project? Have there been changes to legislation, technology, observational programmes, staff reconfiguration, etc.?]

Products and services

[3. Indicate what products and services are required (if any). This may be an existing or new product or service. Provide an example if available.]

Specific staff (optional)

[4. If the project or its outputs require interaction or involvement of specific staff, then list all inputs and actions necessary to perform required duties. These include data inputs and outputs, accessibility and usability requirements as well as training and ongoing assessments.]

Service requirements

[5. Define the service requirements applicable to this project. These may include information technology, communication, display systems, interface, input data capability, data format, data archiving, documentation, training and dissemination methods. Include references and supporting documentation that provide the bases for the service requirements. Include key material and weblinks in the appendices and references.]

Service level requirements

[6. Operational hours, support requirements and return to service expectation. Include responsibilities and whether approval has been obtained by the section responsible. Also include training requirements for system maintenance and support.]

Quality management requirements

[7. Include additional requirements for ensuring QM procedures are followed. For example, certification of instrumentation or changes to competency training.]

_____

Author: _____

Date: __ /__ / __

Title project – status report

1. Project overview				
Project title				
Quality management system				
Start date / end date				
Project team	*Name*	*Position/section*	*Phone*	*Email*
Project sponsor				
Project manager				

2. Project summary	
Project objectives	[List the objectives of the project. Objectives need to be specific (addressing customer requirements) and measurable]
Project scope	[Identify the broad boundaries of the project and what the project is designed to achieve with a specific focus on any customer requirements. It is also useful to consider what may be outside the scope of the project.]
Project deliverables	[List the project deliverables]
Progress summary	[Summarize the progress of the project so far. The actual progress against the planned schedule (including cost, time and performance) should be included.]

3. Status report against milestones

Milestone	*Baseline date*	*Revised target date*	*Status*	*Achievements*	*Issues and outlook*
1.					
2.					
3.					
4.					
5.					
6.					

4. Status report against functional target

Functional target	*Status*	*Achievements*	*Risk*

Note: This table is used as input to management review meetings.

Key:

On schedule and on budget	Minor delays or budgetary issues	Serious delays or budget overspend

Title project – acceptance

1. Project overview				
Project title				
Quality management system				
Start date / end date				
Project team	*Name*	*Position/section*	*Phone*	*Email*
Project sponsor				
Project manager				

2. Project description	
Project objectives	[Include project identifier as per section's operational plan. List the objectives of the project. Objectives need to be specific (addressing customer requirements) and measurable.]
Project description	[Provide a concise description of the project]
Scope	[Identify the broad boundaries of the project and what the project is designed to achieve with a specific focus on any client requirements. It is also useful to consider what may be outside the scope of the project.]
Deliverables	[List the project deliverables]

3. Acceptance information			
Method	[Describe the mechanism used to obtain formal agreement for deployment]		
Representatives	[Identify who was involved in acceptance, including which functional areas; include name, project role or title, section, organization]		
Documentation	[Describe documents used as supporting material during acceptance, including whether the documents required a formal signature for approval]		

4. Acceptance checklist			
Item	*Question*	*Functional area*	
4.1	Did you formally approve plan(s) that identify operational requirements, service readiness, training, knowledge transfer, roll-out strategy, and other core activities/factors that are necessary to effectively move a technology-based product and/or service to an operational status? For example, did you approve a deployment plan, training plan, operations and maintenance plan, and/or product release plan?	Yes	No
4.2	Did you formally accept all test results?	Yes	No
4.3	Do you accept the product and/or service as ready to be operational?	Yes	No
4.4	Do you agree the product and/or service has sufficiently met the stated business goals and objectives?	Yes	No
4.5	Do you fully understand and agree to accept all operational requirements, operational risks, maintenance costs, and other limitations and/or constraints imposed as a result of making the product and/or service operational?	Yes	No

Note: Please respond to each question. For each "no" response, include an issue in the open issues section below.

5. Open issues	
Issue	*Planned resolution*

Note: Describe any open issues and plans for resolution within the context of formally accepting deployment of the product and/or service. Include an open issue for any "no" responses in the acceptance checklist section above.

6. Project acceptance			
Approver	*Signature*	*Date*	*Comments*

Note: Approval of this project acceptance indicates an understanding and formal agreement that the product and/or service has been developed and implemented in accordance with the project plan and is now complete or operationally implemented.

APPENDIX 11. EXTERNAL PROVIDERS REGISTER

Receiver of services programme/section	External provider name	Product or service or process provided	Documentation				Control – monitoring and verification						External property protected?	Flagged at QMRM?	Comments/action taken	Date of last update
			Product specification	Required	Controlled	Location	Yes/No	Frequency	How?		Result	Location	Yes/No	Yes/No		
									Formal reports Y/N	Specific criteria Y/N						

External provider information									
	The organization shall communicate the following requirements to the external provider for :								
QMS (programme/section) receiving external products and services	Product or service or process required	the approval of:			Competence		Communications	Performance	Verification/validation
		Products and services	Methods, processes and equipment	Release of products and services	Include required qualifications of persons	If required, state qualification	With the QMS	Control and monitoring applied by the QMS	Activities that the QMS will undertake at premises

APPENDIX 12. GAP ANALYSIS (PART A)

Gap analysis tool	
Quality management system (QMS)	
Scope of gap analysis	
Gap analysis date	
Gape analysis completion date	
Gape analysis conducted by	
Gap analysis participants	

Key

- Green – minimum compliance
- Amber – partial compliance
- Red – no compliance

This gap analysis tool is aligned with standard ISO 9001:2015, *Quality Management Systems – Requirements*, and it is imperative that gap analysis is undertaken with due reference to the standard. The gap analysis tool is divided into seven sections, which reflect the contents of ISO 9001:2015.

A traffic light system is used to highlight the gaps that exist between the requirements of the standard and the current management system. The traffic light system indicates the level of compliance with the specific requirements of the standard. Throughout this gap analysis, the term quality management system (QMS) embraces all the activities of the QMS/organization. For the purposes of the exercise, the terms management system, QMS and organization can be interchanged and are considered to mean the same thing.

Reference clause in ISO 9001:2015	*Gap analysis question*	*Status*	*Comments*
4. Context of the organization			
4.1 Understanding the organization and its context	1. Has the QMS determined the external and internal issues (values, culture, knowledge and performance) that affect the ability to achieve intended results?		
	2. Has the QMS considered international, national, regional or local issues arising from legal, technological, competitive, market, cultural, social and economic environments?		
	3. How often does the QMS monitor and review these issues?		

Reference clause in ISO 9001:2015	*Gap analysis question*	*Status*	*Comments*
4.2 Understanding the needs and expectations of interested parties	4. Who are the interested parties (stakeholders); for example, customers, owners, people in an organization, suppliers, bankers, unions, partners or society (ISO 9000:2015)?		
	5. Has the QMS determined all the interested parties' requirements?		
	6. Does the QMS monitor and review stakeholder needs, and if so, what process is used and how frequently is it performed?		
4.3 Determining the scope of the quality management system	7. Has the QMS scope been clearly defined? Have the following been considered: external/internal issues (clause 4.1), requirements of interested parties (clause 4.2) and products and services of the organization?		
	8. Does the scope state the products/services covered? Does it justify any areas not applicable and is it available as documented information?		
4.4 Quality management system and its processes	9. Have the processes (inputs/outputs and sequences/ interactions) required to deliver the outcomes been determined?		
	10. Have key performance indicators (KPIs) and methods of measurement been established to ensure the effectiveness of processes?		
	11. Have the resources required to support each process and their availability been determined?		
	12. Have responsibilities and authorities been determined for all processes?		
	13. Have risks and opportunities been identified (with respect to clause 6.1)?		
	14. Are processes evaluated and improved?		
	15. Is documented information retained to provide confidence that processes are being carried out as planned?		
5. Leadership			
5.1 Leadership and commitment	Does top management:		
	16. Promote a process approach and risk-based thinking?		
	17. Ensure resources are available as appropriate?		
	18. Ensure intended results are achieved?		
	19. Promote improvement?		
	20. Ensure customer/statutory/regulatory requirements are determined, understood and consistently met?		
	21. Ensure risks and opportunities that can affect conformity of products/services and the ability to enhance customer satisfaction are determined and addressed?		
	22. Ensure the focus on enhancing customer satisfaction is maintained?		
5.2 Policy	23. Has a quality policy been formulated and communicated to all staff?		

Reference clause in ISO 9001:2015	*Gap analysis question*	*Status*	*Comments*
5.3 Organizational roles, responsibilities and authorities	24. Does top management ensure that responsibilities and authorities for staff are assigned, communicated and understood within the organization? In particular, are responsibilities and authorities assigned for ensuring processes deliver their intended outputs, reporting on opportunities for improvement and ensuring the promotion of customer focus?		
6. Planning			
6.1 Actions to address risks and opportunities	25. Does the QMS have a process to identify risks and opportunities, including their control and treatment?		
	26. Does the risk and opportunities process consider internal/external issues and the needs and expectations of interested parties?		
	27. Is this process undertaken on a scheduled basis and on a needs basis?		
	28. Is this process used to ensure that products/services conform to defined requirements or achieve improvements?		
	29. Is this process documented and communicated to all staff?		
6.2 Quality objectives and planning to achieve them	Are the objectives and KPIs:		
	30. Relevant to the conformity of products/services and customer satisfaction?		
	31. Aligned with defined requirements?		
	32. Measurable?		
	33. Monitored and communicated?		
	34. Maintained as documented information and updated as appropriate?		
	When planning how to achieve these objectives, is it determined:		
	35. What tasks and processes will be conducted and what resources are required?		
	36. Who will be responsible for achieving the objective and when?		
	37. How the results of the planning will be evaluated?		
6.3 Planning of changes	38. Is change undertaken in a planned manner?		
	39. Does the QMS consider the purpose of the change and potential consequences including associated risks?		
	40. Does the QMS consider the allocation of responsibilities/authorities and availability of resources?		
7. Support			
7.1 Resources 7.1.1 General	41. Are existing internal resource capabilities and limitations determined, and which, if any, are sourced externally?		
	42. Has the necessary infrastructure been determined, provided and maintained for QMS operations, to assure conformity of products/services and customer satisfaction?		
7.1.2 People	43. Has the QMS determined and provided the people needed for the operation of its processes and to achieve conformity of products/services?		

Reference clause in ISO 9001:2015	*Gap analysis question*	*Status*	*Comments*
7.1.3 Infrastructure	44. Has the QMS determined, provided and maintained the infrastructure (buildings, equipment, hardware, software, communications, information technology systems) necessary for operations and to assure conformity of products/ services and customer satisfaction?		
7.1.4 Environment for the operation of processes	45. Has the necessary process environment (social, for example, non-discriminatory, calm or non-confrontational; psychological, for example, stress-reducing, burnout prevention or emotionally protective; and physical, for example, temperature, heat, humidity, light, airflow, hygiene or noise) been determined, provided and maintained for QMS operations, to assure conformity of products/ services and customer satisfaction?		
7.1.5 Monitoring and measuring resources 7.1.5.1 General	46. Have the monitoring and measuring resources needed to verify the conformity to product requirements been determined, to ensure they are fit for purpose?		
	47. Is appropriate documented information as evidence of fitness for purpose of monitoring and measuring devices maintained?		
7.1.5.2 Measurement traceability	48. Is measurement traceability required?		
	49. Has measuring equipment been calibrated or verified (or both) at specified intervals against measurement standards traceable to international (or national) standards?		
	50. Has measuring equipment been identified in order to determine its status and safeguarded from adjustment/damage/deterioration that could invalidate the calibration status?		
	51. If the measuring equipment is found to be unfit for purpose, has the validity of previous measurement results been investigated and appropriate action taken?		
7.1.6 Organizational knowledge	52. Has the corporate knowledge necessary for operation of the organization to assure conformity of products/services and customer satisfaction been determined?		
	53. Is corporate knowledge maintained, protected and made available as necessary?		
	54. How is it ensured that the current knowledge base is kept up to date including emerging trends?		
7.2 Competence	55. Has the necessary competence of QMS staff been determined?		
	56. Is it ensured that the staff is competent on the basis of appropriate education, training or experience?		
	57. Is appropriate documented information as evidence of competence maintained?		
7.3 Awareness	58. Is the staff aware of the relevant objectives and effectiveness in contributing to them?		
7.4 Communication	59. Has a communications plan relevant to internal and external stakeholders been developed?		
7.5 Documented information 7.5.1 General	60. Has the QMS documented information that has been determined as being necessary for the effectiveness of the management system?		

Reference clause in ISO 9001:2015	*Gap analysis question*	*Status*	*Comments*
7.5.2 Creating and updating	When creating and updating documented information, are the following ensured:		
	61. Identification and description (title, date, author, reference number, currency, version number)?		
	62. Format and media (language, software version, graphics, paper, electronic)?		
	63. Review and approval for suitability and adequacy?		
7.5.3 Control of documented information	Is documented information controlled to ensure:		
	64. It is available and suitable for use, where and when it is needed?		
	65. It is adequately protected (for example, from loss of confidentiality, improper use or loss of integrity)?		
	66. Distribution, access, retrieval and use?		
	67. Who has permission to view the documented information?		
	68. Who has permission and authority to change the documented information?		
	69. Storage and preservation, including preservation of legibility?		
	70. Retention and disposal?		
8. Operation			
8.1 Operational planning and control	71. Does the QMS plan, implement and control the processes needed to mitigate risks and identify opportunities?		
	72. Are criteria established for these processes?		
	73. Is documented information retained to provide confidence that the processes have been carried out as planned?		
8.2 Requirements for products and services 8.2.1 Customer communication	74. Is there a process for interacting with potential or existing customers to determine their requirements relating to products/services?		
	75. Does communication with customers include: information relating to products/services; handling enquiries, contracts and orders including changes; obtaining feedback including complaints; handling/controlling customer property; and establishing specific requirements for contingency actions, when relevant?		
8.2.2 Determining the requirements for products and services	76. Has the QMS determined the requirements specified by the customer including the requirements for delivery and post-delivery activities?		
	77. Has the QMS determined the statutory and regulatory requirements applicable to the products/services?		
8.2.3 Review of requirements for products and services	78. Does the QMS review the requirements related to the products/services?		
	Are reviews conducted (prior to commitment to supply products/services to the customer) to ensure that:		
	79. Requirements are defined and agreed?		
	80. Contract requirements differing from those previously expressed are resolved?		
	81. The organization is able to meet the defined requirements?		

Reference clause in ISO 9001:2015	*Gap analysis question*	*Status*	*Comments*
8.2.4 Changes to requirements for products and services	82. When changes to requirements are needed, has the relevant documented information been amended and relevant persons informed of the changes?		
8.3 Design and development of products and services 8.3.1 General	83. Has the QMS established, implemented and maintained a design and development process?		
8.3.2 Design and development planning	84. In determining the stages and controls for this process, are the following considered: nature, duration and complexity of design and development activities; required process stages including applicable review stages; internal and external resources needed; and need to involve customers and users?		
8.3.3 Design and development inputs	85. Does the QMS determine the requirements essential for the products/services to be designed and developed? These include functional and performance requirements, statutory and regulatory requirements, standards or codes of practices the organization has committed to implement and the potential consequences of failure due to the nature of the products/services.		
	86. Does the QMS retain documented information on all design and development inputs?		
8.3.4 Design and development controls	87. Does the QMS have controls in place for design and development activities? These include functional and performance requirements, statutory and regulatory requirements, standards or codes of practices the organization has committed to implement and the potential consequences of failure due to the nature of the products/services.		
8.3.5 Design and development outputs	88. Does the QMS ensure that design and development outputs meet the input requirements, are adequate for the provision of products/services and include monitoring, as appropriate?		
	89. Does the QMS retain documented information on all design and development outputs?		
8.3.6 Design and development changes	90. Does the QMS identify, review and control any changes made during (or after) the design and development of products/services to ensure no adverse impact on conformity to requirements?		
	91. Does the QMS retain documented information on changes such as design and development changes, review results, authorization for any changes and actions to prevent adverse impacts?		
8.4 Control of externally provided processes, products and services 8.4.1 General	92. How is it ensured that externally provided products/services conform to specified requirements?		
	93. Is documented information on these evaluation activities retained?		

Reference clause in ISO 9001:2015	*Gap analysis question*	*Status*	*Comments*
8.4.2 Type and extent of control	94. Has it been ensured that externally provided processes remain within the control of the management system?		
	95. Have the controls that apply to the provider and the supplied product/service both been defined?		
	96. Has the potential impact of externally provided products/services on the ability to meet customer/ statutory/regulatory requirements been defined?		
	97. Have risk and potential opportunities been identified?		
	98. Has the degree to which the control of an externally provided process is shared between QMS and the provider been identified?		
	99. Has the QMS established and applied criteria for the evaluation, selection and re-evaluation of external providers based on QMS requirements?		
	100. Does the QMS maintain documented information describing the results of evaluations?		
8.4.3 Information for external providers	Are reviews conducted (prior to commitment to supply products/services to the customer) to ensure that:		
	101. Requirements for approval or release of products/ services, procedures, processes or equipment are met?		
	102. Requirements for competence of personnel, including necessary qualifications, are met?		
	103. Control and monitoring of external provider performance is applied by the QMS?		
	104. Verification activities that the QMS or its customer intend to perform at external provider premises are conducted?		
	105. Requirements for handling of external provider property provided to the QMS are met?		
	106. Requirements for handling of external provider property provided to the QMS are met?		
8.5 Production and service provision 8.5.1 Control of production and service provision	107. Is service provision performed under controlled conditions and does it include: documented information defining characteristics of products and results to be achieved; using monitoring and measurement at appropriate stages to ensure acceptance criteria are met; suitable infrastructure and environment; competent persons (including required qualifications); actions to prevent human error; and implementation of release, delivery and post-delivery activities?		
8.5.2 Identification and traceability	108. Are outputs uniquely identified?		
	109. Is documented information retained?		
8.5.3 Property belonging to customers or external providers	110. Does the QMS identify, verify, protect and safeguard external provider property?		
	111. If property is lost, damaged or otherwise found unsuitable, is it reported and is documented information retained?		
8.5.4 Preservation	112. Is the preservation of products during processing and delivery ensured to the intended destination, in order to maintain conformity to requirements?		

Reference clause in ISO 9001:2015	*Gap analysis question*	*Status*	*Comments*
8.5.5 Post-delivery activities	113. Where applicable, does the organization determine and meet requirements for post-delivery activities associated with the nature and intended lifetime of the products/services?		
8.5.6 Control of changes	114. Is change undertaken in a planned and systematic manner?		
	115. Are the potential consequences taken into account?		
	116. Is integrity of products/services ensured?		
	117. Does the QMS maintain documented information describing the results of changes and of the personnel authorizing the change?		
8.6 Release of products and services	118. Does the QMS ensure that the release of products/services does not proceed until planned arrangements for verification of conformity have been satisfactorily completed?		
	119. Does the QMS maintain documented information of the person(s) authorizing the release of products/services for delivery to customers?		
8.7 Control of nonconforming outputs	120. Does the QMS ensure that products/services that do not conform to requirements are identified and controlled to prevent their unintended use or delivery?		
9. Performance evaluation			
9.1 Monitoring, measurement, analysis and evaluation 9.1.1 General	Does the QMS determine and take into consideration, any risks and opportunities in terms of what needs to be monitored and measured in order to:		
	121. Demonstrate conformity of products/services to requirements?		
	122. Evaluate customer satisfaction?		
	123. Determine the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results?		
	124. Does the QMS retain appropriate documented information records as evidence of the results?		
9.1.2 Customer satisfaction	125. Does the QMS monitor and record levels of customer satisfaction?		
9.1.3 Analysis and evaluation	Does the QMS analyse and evaluate the results obtained from monitoring and measurement to:		
	126. Ensure that the operation and control of processes is effective?		
	127. Identify improvements?		
	128. Are the results of analysis and evaluation used as an input to the management review process?		
9.2 Internal audit	129. Does the QMS conduct, plan and schedule internal audits?		
	130. Has the QMS selected auditors that ensure objectivity and impartiality?		
	131. Does the QMS ensure audit findings are reported to the relevant management?		
	132. Does the QMS retain documented information as evidence of audit results and that the audits have been conducted?		

Reference clause in ISO 9001:2015	*Gap analysis question*	*Status*	*Comments*
9.3 Management review 9.3.1 General 9.3.2 Management review inputs	133. Does the QMS conduct management reviews on a scheduled and needs basis?		
	134. Do the management reviews inputs include: customer satisfaction feedback, status of objectives, performance of processes, issues with non-conformities and corrective actions, results of monitoring and measuring audit findings, and performance of external providers?		
9.3.3 Management review outputs	135. Do the management review outputs include: opportunities for improvement, changes to the QMS and additional resource requirements?		
10. Improvement			
10.1 General	136. Does the QMS identify opportunities for improvement, in particular, to enhance customer satisfaction?		
10.2 Nonconformity and corrective action	137. What actions does the QMS take to control, correct and deal with the consequences of a non-conformity?		
	Does the QMS evaluate the need for action to eliminate the causes of the non-conformity to ensure it does not occur again by:		
	138. Determining the causes of the non-conformity?		
	139. Implementing any action required so that it does not recur or occur elsewhere?		
	140. Reviewing the effectiveness of any corrective action taken?		
	141. Retaining documented information as evidence of the nature of the non-conformities and any subsequent actions taken?		
10.3 Continual improvement	142. Does the QMS continually endeavour to improve the suitability, adequacy and effectiveness of its management system?		
	Does the QMS improve processes and products/ services by responding to:		
	143. Results of analysis of data?		
	144. Changes in identified risks?		
	145. Identification of new opportunities?		

APPENDIX 13. GAP ANALYSIS FINDINGS (PART B)

Gap analysis findings	
Quality management system (QMS)	
Scope of gap analysis	
Gap analysis time period	
Gap analysis completion date	
Gap analysis conducted by	
Gap analysis participants	
Notes	

4 – Context of the organization				
Reference clause in ISO 9001:2015	*Gap identified*	*Proposed remedial action*	*Officer responsible*	*Gap filled date*
5 – Leadership				
Reference clause in ISO 9001:2015	*Gap identified*	*Proposed remedial action*	*Officer responsible*	*Gap filled date*
6 – Planning				
Reference clause in ISO 9001:2015	*Gap identified*	*Proposed remedial action*	*Officer responsible*	*Gap filled date*

7 – Support				
Reference clause in ISO 9001:2015	*Gap identified*	*Proposed remedial action*	*Officer responsible*	*Gap filled date*
8 – Operation				
Reference clause in ISO 9001:2015	*Gap identified*	*Proposed remedial action*	*Officer responsible*	*Gap filled date*
9 – Performance evaluation				
Reference clause in ISO 9001:2015	*Gap identified*	*Proposed remedial action*	*Officer responsible*	*Gap filled date*
10 – Improvement				
Reference clause in ISO 9001:2015	*Gap identified*	*Proposed remedial action*	*Officer responsible*	*Gap filled date*