Submission #1

INFORMATION TO BE PROVIDED, AS APPLICABLE

1. Title of Submission

ISO 9001:2015 Certification

2. Please briefly describe the issue, problem, risk or gap that this submission addresses.

PEO received a badly failing grade in its regulatory review by Harry Cayton.

3. Please summarize the action that you are requesting from Council and how it will address the issue, problem, risk or gap stated above.

I am asking that PEO Council establish a Policy that it will become ISO 9001:1500 certified by 2022 on its 100 Anniversary

4. Please cite and briefly summarize any research that supports the proposed action.

The following documents were researched
a)
b) SGS CBE ISO 9001 White Paper EN
c) SGS CBE ISO 9001 Readiness Checklist A4 EN
d)

5. As applicable please describe how the proposed action will contribute to serving and protecting the public interest as it pertains to the regulation of professional engineering and the engineering profession.

Being ISO 9001:1500 certified will set an example for the engineering community and start creating a culture and environment for engineers to serve and protect the public interest

6. Please identify any legal considerations (eg., the need for changes to the statute, regulation, by-laws etc.) that may affect Council's ability to implement the proposed action.

There are no known restrictions to PEO seeking ISO 9001:1500 certification.

7. Please identify any considerations that are relevant to the timing (or urgency) of the proposed action.

This policy is way past due. I personally suggested it several years ago. It can't be done overnight and two years is a reasonable timeline based on the time it took a company that I worked for to become ISO 9001 certified and they were in a much better starting point than PEO .
It would be a fitting objective to mark the Association of Professional Engineering of Ontario 100 Anniversary.

8. Please provide any other information that you feel will assist members of the AGM and Council in understanding your submission, in particular your proposed action.

ISO 9001:2015 positions the new version of the standard as an integral part of an organization's efforts towards the broader aim of sustainable development and promotes it as a tool for improving an organization's overall performance. This is in addition to the fact that the adoption of a QMS is a strategic decision for an organization.

9. Please list any attachments to this document.

Attachment 1: SGS CBE ISO 9001 White Paper EN
Attachment 2 : SGS CBE ISO 9001 Readiness Checklist A4 EN

Member #1 (name/signature): Ray Linseman, P.Eng.

Member #2 (name/signature): John Ireland P.Eng.

Date: 2020-04-09 before 8am

PLEASE FORWARD THE COMPLETED SUBMISSION ELECTRONICALLY, WITH ANY ATTACHMENTS
TO:
CEO/REGISTRAR, c/o *AGMSUBMISSIONS@PEO.ON.CA*
AT LEAST TEN (10) DAYS PRIOR TO THE ANNUAL GENERAL MEETING

ISO 9000 Series of Quality Standards

The ISO 9000 family of standards is the same across the globe even though they are called by different names. Each member country has their own entity (https://www.iso.org/members.html) authorized by ISO (https://the9000store.com/articles/who-is-iso/) to manage the standards, but they are all the same exact ISO 9000 quality documents.

What is the ISO 9000 series of quality management system standards?

The ISO 9000 series was created by the International Organization for Standardization (ISO) (https://the9000store.com/articles/who-is-iso/) as international requirements (https://the9000store.com/iso-9001-2015-requirements/) and guidelines for quality management systems. It was originally introduced in 1987 and over the years has established itself in the global economy having been adopted in over 178 countries with over one million registrations.

The phrase “ISO 9000 family” or “ISO 9000 series” refers to a group of quality management standards which are process standards (https://the9000store.com/iso-9001-2015-requirements/iso-9001-2015-context-of-the-organization/processes-procedures-work-instructions/) (not product standards).

- ISO 9000 (https://the9000store.com/what-are-iso-9000-standards/what-is-iso-9000/)*Quality management systems – Fundamentals and Vocabulary,* referenced in all ISO 9000 Standards.
- ISO 9001 (https://the9000store.com/what-are-iso-9000-standards/buy-standards/) *Quality management systems – Requirements*, contains the requirements an organization must comply with to become ISO 9001 certified.
- ISO 9002 (https://the9000store.com/what-are-iso-9000-standards/what-is-iso-9002/) – ***Guidelines*** for the application of ISO 9001:2015
- ISO 9004 (https://the9000store.com/what-are-iso-9000-standards/what-is-iso-9004/)– *Managing for the sustained success of an organization*, provides ***guidelines*** for sustaining QMS success through evaluation and performance improvement.

ISO 9001:2015 (https://the9000store.com/what-are-iso-9000-standards/what-is-iso-9001/) is the current version of the ISO 9001 standard. ISO 9001 lists requirements (https://the9000store.com/iso-9001-2015-requirements/), while the other standards in the 9000 family provide guidelines and information. People often say “**ISO 9000 certified**“, but what they mean is they have met the requirements of the ISO 9001 standard. Read more about ISO 9001 Certification. (https://the9000store.com/articles/iso-9001-certification/)

The ISO 9000 Series of Quality Standards is not industry specific and is applicable to any manufacturing, distribution or service organization. It is managed by Technical Committee (TC) 176, comprised of international members from many industries and backgrounds.

What are the older (obsolete) ISO 9000 quality standards?

ISO 9000 (1994) originally had three QMS models depending on the primary function:

- **ISO 9001:1994** Model for quality assurance in design, development, production, installation, and servicing was for companies and organizations whose activities included the creation of new products.
- **ISO 9002:1994** Model for quality assurance in production, installation, and servicing had basically the same material as ISO 9001 but without covering the creation of new products. Learn more about ISO 9002 (https://the9000store.com/what-are-iso-9000-standards/what-is-iso-9002/).
- **ISO 9003:1994** Model for quality assurance in final inspection and test covered only the final inspection of finished product, with no concern for how the product was produced. Learn more about ISO 9003. (https://the9000store.com/what-are-iso-9000-standards/what-is-iso-9003/)

All of these were combined into ISO 9001:2000 (https://the9000store.com/what-are-iso-9000-standards/what-is-iso-9001/what-is-iso-9001-2000/), which was updated to ISO 9001:2008 (https://the9000store.com/iso-9000-tips-iso-9001-requirements/) and is now ISO 9001:2015 (https://the9000store.com/iso-9001-2015-requirements/).

What standards support the ISO 9000 Series of Quality Standards?

Other ISO quality standards were created to support the ISO 9000 family, and not all start with ISO 9001:

- ISO 10000 Series of Standards (https://the9000store.com/what-are-iso-9000-standards/what-are-iso-10000-standards/)
- What is ISO 19011? (https://the9000store.com/articles/what-is-iso-19011/)
- What is ISO/IEC 17021? (https://the9000store.com/articles/what-is-iso-iec-17021/)

Standards based upon ISO 9001

There are other ISO quality standards created based up the 9000 family which are specific to certain industries (Aerospace, Automotive Medical Devices, etc):

- Standards based upon ISO 9001 (https://the9000store.com/what-are-iso-9000-standards/standards-based-upon-iso-9001/)

Where in the Process

1 Prepare your Organization (https://the9000store.com/step-by-step/step1-what-is-iso-9001/)

2 Gap Analysis (https://the9000store.com/step-by-step/step2-perform-gap-analysis/)

3 Project Plan (https://the9000store.com/step-by-step/step3-iso-9001-implementation-plan/)

4 Training (https://the9000store.com/step-by-step/step4-iso-9001-training/)

5 Documentation (https://the9000store.com/step-by-step/step5-document-iso-9001/)

6 Use and Improve QMS (https://the9000store.com/step-by-step/step6-implement-iso-9001-qms/)

7 Internal Audits (https://the9000store.com/step-by-step/step7-iso-9001-internal-audits/)

8 ISO Registration (https://the9000store.com/step-by-step/step8-iso-9001-registration-audit/)

Customer Review:

"I have just passed my ISO-9001 Audit with zero non-conformances for the second year in a row using your ISO products to write my entire QMS. Thank you for producing documents of this quality"

Bettye Patrick
United Plating, Inc

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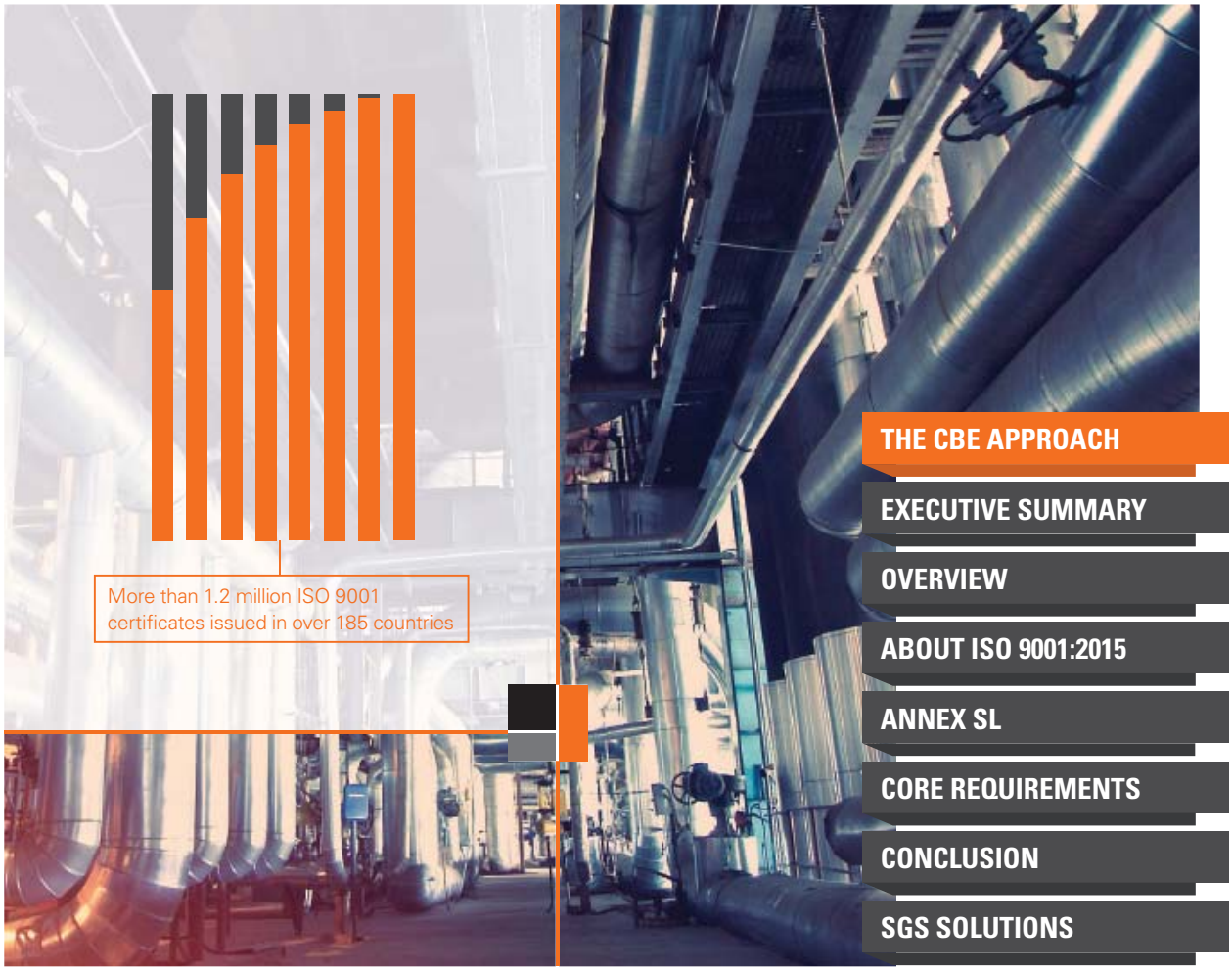


HOW CAN YOU IMPROVE THE SAFETY OF YOUR PRODUCTS?

ENHANCE YOUR QUALITY MANAGEMENT SYSTEM WITH ISO 9001:2015

SGS

THE CERTIFICATION AND BUSINESS ENHANCEMENT APPROACH

Organizations today are met with a variety of operational and business challenges. External forces, like competitors and regulatory bodies, also add a secondary level of pressures that must be anticipated. Additionally, both B2B and B2C firms are experiencing a large influx of customer data, across multiple touchpoints. The dividing factor between those who are successful and those who are not, is how they analyze and use that data for business enhancement. At SGS, we have developed a variety of solutions to not only meet these needs, but establish more efficient and profitable ways of working. Using our 140 years of experience and operational data set, we partner with clients to gain intelligent insights into their current business functions while simultaneously strategizing for the future. To meet the needs of our current customers and provide effective and modern solutions to current and future business issues, we offer three pillars of insights-driven, customizable products and solutions.

SGS BUSINESS BENEFITS

- Deliver innovative solutions and services that enhance businesses
- Offer customized solutions, driven by proprietary insights
- Provide services fundamental to ongoing success and sustained growth
- Enable continuous improvement
- Transform value chains

CERTIFICATION

Our wide-ranging portfolio of industry specific ISOs and regulatory standards.

INTELLIGENCE

A complete set of digital tools and solutions used to improve business efficiency and functionality.

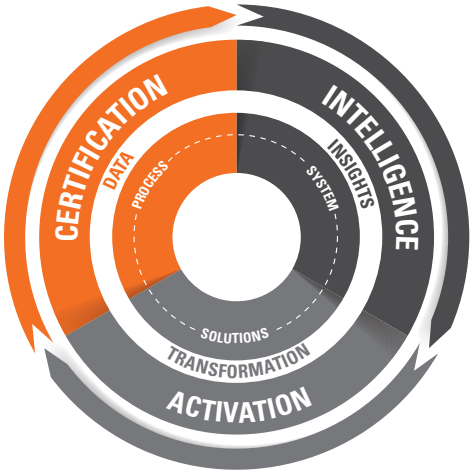
ACTIVATION

Our total business enhancement solutions, created specifically to enhance businesses and industries.

ISO Standards	BE Engine	SGS Academy
Regulatory Standards	Intelligent Assessments	Technical Consulting
Industry Standards	iPLUS	Performance Assessments
	Customized Assessment Tracking System	Supplier Verification

THE BUSINESS ENHANCEMENT PLATFORM

For decades, SGS has been known as the global leader in certification, working with clients in virtually any sector. This deep and broad experience in quality control management, regulatory compliance, and training has resulted in a staggering array of data points across industries. Utilizing this dataset, we have evolved our service offerings to include Business Enhancement—the process of transformation that improves or increases the value of an organization's people, processes, product or service. Our Business Enhancement solutions offer the most up-to-date, practical insights to help you achieve your goals and ultimately BE the Benchmark.

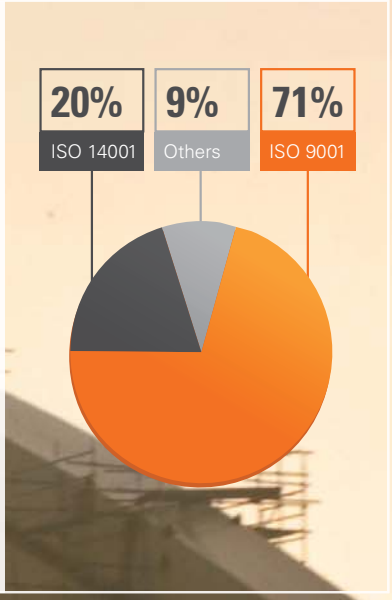


ABSTRACT

This document aims to provide an insight into the contents of ISO 9001:2015. It is not intended to be a full explanation of all of the requirements of ISO 9001:2015, rather it provides an overview of the key changes to The Quality Management Systems (QMS).

INTRODUCTION

With more than 1,250,000 certificates expected to have been issued, in more than 185 countries, ISO 9001 is by far the most recognised management system standard in the world. ISO 9001 provides the requirements needed to establish, implement and certify an organization's QMS. It is the management system most used to instill trust and enhance customer satisfaction in the relationship between buyers and sellers along the supply chain. When it comes to quality related matters, all ISO standards are, and have been, periodically reviewed to ensure that they are still relevant and reflect current business practices and market demands. The latest ISO 9001 revision process is simply the latest in a series of revisions (1987, 1994, 2000 and 2008). However, as the 2008 revision to ISO 9001 made only minor amendments, the expected 2015 revision will make the first significant changes since the year 2000. The figure to the right is based on the ISO Survey of Management System Standard Certificates 2014. It clearly shows that ISO 9001 certificates represent almost 71% of the total number of certificates issued globally.



EXECUTIVE SUMMARY

ISO 9001:2015 positions the new version of the standard as an integral part of an organization's efforts towards the broader aim of sustainable development and promotes it as a tool for improving an organization's overall performance. This is in addition to the fact that the adoption of a QMS is a strategic decision for an organization. Besides renaming and repositioning certain activities, other significant new requirements have been introduced. Some of these are consequences of the adoption of the Annex SL framework and core text (see 'III. ANNEX SL' below), but others are specific QMS requirements.

There are now clauses relating to an organization's 'context' and any associated internal and external issues which may have an impact on the organization and its QMS (clause 4.1) and with the needs and expectations of those 'interested parties' who can be affected by the organization's activities (clause 4.2). These changes will require organizations to move away from a purely inward-focusing approach to QMS development and implementation, to one where external factors have a greater influence on the way in which the QMS is focused and prioritised; to be as effective as possible in meeting key internal and external objectives.

THE KEY TO FUTURE GROWTH AND PROSPERITY WILL BE OUR ABILITY TO EVOLVE OUR SERVICE PORTFOLIO TO NEW AREAS THAT WILL ADD VALUE TO OUR CUSTOMERS, WHICH WE REFER TO AS BUSINESS ENHANCEMENT SERVICES.

In addition, there are now requirements relating to an organization's need to identify potential risks and opportunities which may have an impact on its ability to consistently meet customer requirements (clause 6.1). Although ISO 9001:2015 no longer has any specific requirements relating to 'Preventive Action' (ISO 9001:2008 clause 8.5.3), the identification of potential errors and taking action to address them remains in the new requirements relating to risks and opportunities. The new requirement in ISO 9001:2015 stating (clause 10.2) that an organization must determine whether any identified non-conformity could also 'potentially' exist or occur elsewhere, also has obvious similarities with the current 'Preventive Action' requirements.

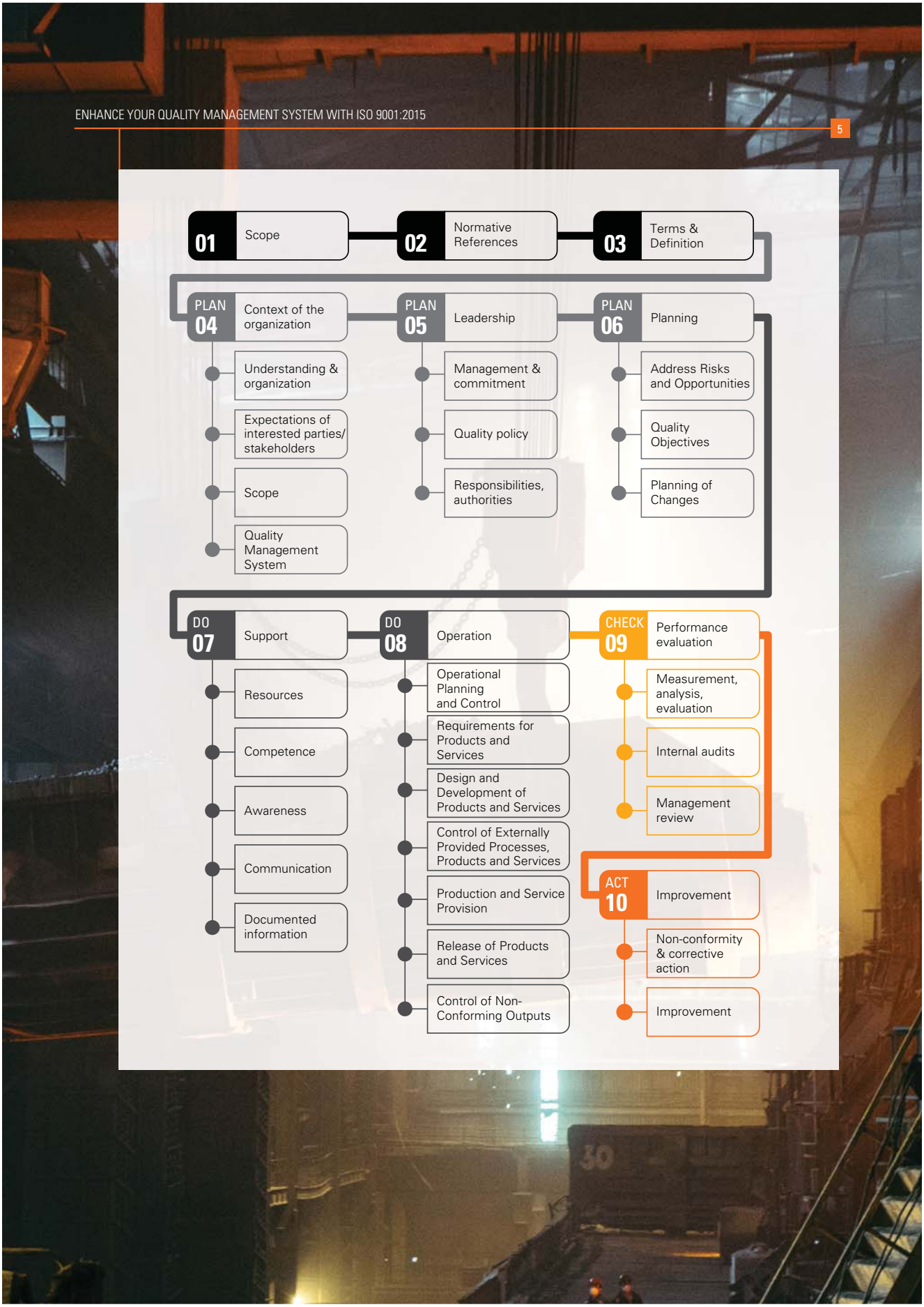
An organization would be required to take a risk-based approach to determine the type and extent of controls appropriate to all types of external providers (whether it is by purchasing from a supplier, for example, or through the outsourcing of processes and functions, etc.) and all external provision of goods and services.

ISO 9001:2015 contains no requirements relating to the need for a Quality Manual, Procedures or Records. There are now numerous references to 'Documented Information' (clause 7.5), which is information that an organization is required to keep, control and maintain, though there are no specific requirements about its format or how it must be stored.

There remains a requirement to identify and maintain the knowledge needed to ensure that the conformity of products and services is achieved. This 'organizational knowledge' includes information that is held by personnel, but it must also include consideration of the context in which an organization operates.

There is no longer any requirement for an organization to appoint a 'Management Representative' (ISO 9001:2008 clause 5.5.2), though this does not prevent organizations from retaining this position within their structure if they choose to. However, organizations need to note that some of the activities and responsibilities typically undertaken by a Management Representative now need to be carried out directly by its top management and can no longer be assigned (ISO 9001:2015 clause 5).

ISO 9001:2015 more directly expects organizations to apply a process approach when planning, implementing and developing their QMS. It also includes a list of requirements identifying the essential elements of such an approach. The intention is to ensure that organizations systematically define and manage not just their processes, but also the interaction between them.


01 Scope
02 Normative References
03 Terms & Definition
PLAN 04 Context of the organization
Understanding & organization
Expectations of interested parties/ stakeholders
Scope
Quality Management System
PLAN 05 Leadership
Management & commitment
Quality policy
Responsibilities, authorities
PLAN 06 Planning
Address Risks and Opportunities
Quality Objectives
Planning of Changes
DO 07 Support
Resources
Competence
Awareness
Communication
Documented information
DO 08 Operation
Operational Planning and Control
Requirements for Products and Services
Design and Development of Products and Services
Control of Externally Provided Processes, Products and Services
Production and Service Provision
Release of Products and Services
Control of Non-Conforming Outputs
CHECK 09 Performance evaluation
Measurement, analysis, evaluation
Internal audits
Management review
ACT 10 Improvement
Non-conformity & corrective action
Improvement

ANNEX SL

There are many management system standards covering a wide range of areas such as quality, environment, occupational health & safety etc. Over the years organizations have tried to implement and gain certifications for multiple management system standards. Their attempts to combine them into one effective and efficient integrated system have not always been easy since the requirements, terms and definitions, etc. of the various ISO management system standards can be significantly different.

In recognition of this, the ISO Technical Management Board produced Annex SL of the Consolidated ISO Supplement of the ISO/IEC Directives in 2012 (Annex SL), previously ISO Guide 83. Annex SL's aim is to enhance the consistency and alignment of ISO management system standards by providing:

- A unifying and agreed high level structure
- Identical core text
- Common terms and core definitions

Consequently, Annex SL provides a template or framework for all new and revised MSS. The high level structure (i.e. major clause numbers and titles) is fixed and cannot be changed, although discipline-specific sub-clauses may be added.

The intention is that all ISO management system standards (MSS) will be aligned and the compatibility of these standards will be enhanced. For example, the major clause numbers and titles in all future ISO management system standards will be identical. As a result, all MSS will look very similar. In addition, it is expected that this will lead to less inconsistency as common terms will all have the same definition. This approach will be particularly useful for those organizations that choose to operate an 'integrated' management system that meets the requirements of two or more management system standards. (see Figure 1)

Figure 1

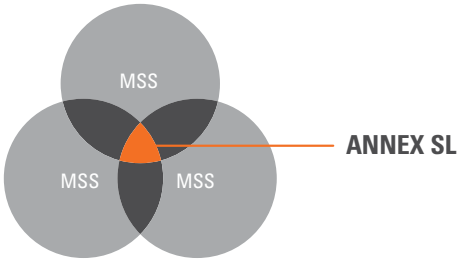
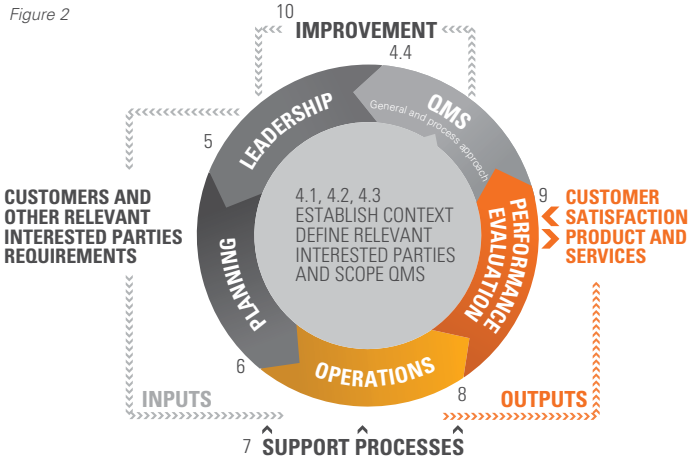


Figure 2



Annex SL has already been used as the template for the new Business Continuity Management standard, ISO 22301, which was issued in 2012 and for the 2013 revision to ISO 27001 – Information Security Management. It has also been used for the revisions to ISO 9001 & 14001 and will be used for the new Occupational Health and Safety Management standard, ISO 45001.

ANNEX SL AND ISO 9001:2015

ISO 9001:2015 uses the Annex SL framework and adopts its high-level structure, core text and common terms and core definitions. The list of main clauses is now as follows:

1. Scope
2. Normative references
3. Terms and definitions
4. Context of the organization
5. Leadership
6. Planning
7. Support
8. Operation
9. Performance evaluation
10. Improvement

However, within sub-clauses to these main activity headings, ISO 9001:2015 also includes those additional requirements which are specific to QMS. (see Figure 2)

One of the consequences of adopting the Annex SL is that some of the requirements of ISO 9001:2008, which are unchanged in ISO 9001:2015, are now located under different headings in differently numbered clauses. For example, 'Management Responsibility' activities from ISO 9001:2008 clause 5, are now to be found under 'Leadership' in a new clause 5, whilst 'Product Realisation' in clause 7 is now covered by the new clause 8 'Operation'.

THE CORE REQUIREMENTS OF ISO 9001: 2015

CLAUSE 1
SCOPE

The overriding aim or 'Scope' of ISO 9001:2015 is to specify the requirements for a QMS that can be used by organizations that want to:

- Demonstrate their ability to consistently provide products or services that meet customer and applicable statutory and regulatory requirements
- Enhance customer satisfaction through the application of such a system, including processes for improvement and the assurance of conformity to those customer and applicable statutory and regulatory requirements

Apart from some minor changes, the wording of this clause is almost exactly the same as is used in ISO 9001:2008.

However, there is no longer any requirement for identification in a Quality Manual of any elements that cannot be applied by an organization implementing a QMS (ISO 9001:2008 clause 1.2). Nor such exclusions limited to requirements found under clause 7 'Product Realisation'. Although all of the requirements in ISO 9001:2015 are intended to be applicable to all types of organizations, it is recognised that there may be circumstances where compliance with a specific requirement is impossible because an organization simply does not undertake a certain type of activity as part of its business.

In such cases, the organization can regard the requirement as 'not applicable'. However, it would affect its ability to supply products or services which comply with client requirements, or which adversely affect its ability to enhance customer satisfaction.

CLAUSE 2
NORMATIVE REFERENCES

As with ISO 9001:2008, the key normative reference remains ISO 9001: Quality Management System - Fundamentals and Vocabulary.

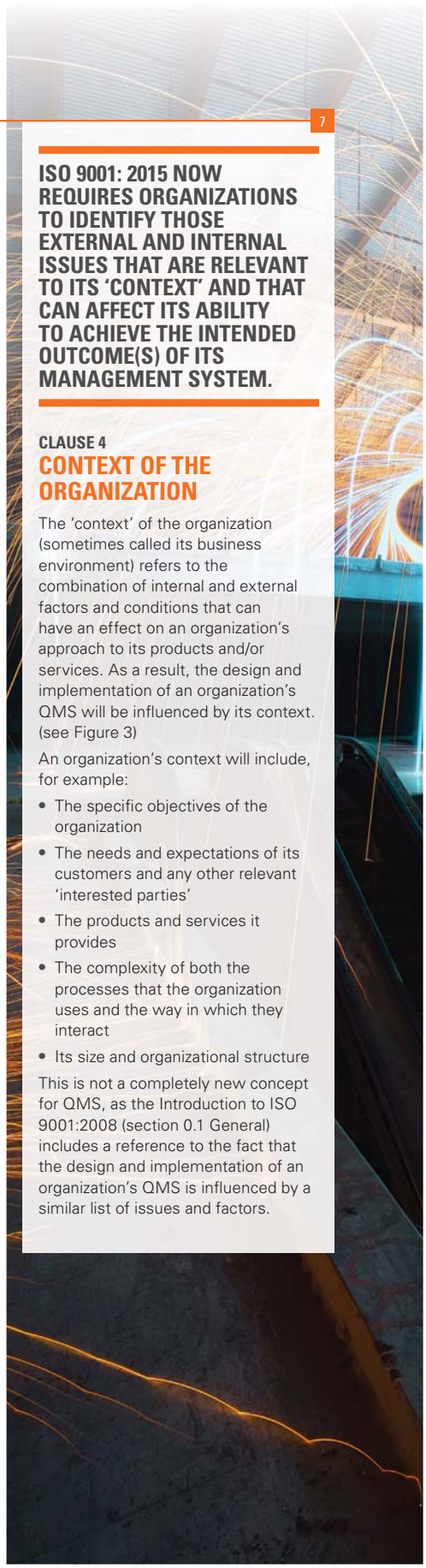
CLAUSE 3
TERMS AND DEFINITIONS

All applicable terms and definitions are incorporated into the revised ISO 9001: 2015. These terms and definitions will include all those from Annex SL.

Annex SL itself contains 22 terms and definitions which must be included in all management system standards. These are the terms and definitions which would naturally be expected to appear in any MSS, irrespective of the discipline addressed by the Standard itself; definitions of terms such as 'audit', 'corrective action', 'management system', 'measurement', 'objective', 'policy'. All of these terms and definitions are included in ISO 9001:2015.

However, many additional QMS-specific terms and definitions have also been added, which include related terms and definitions, such as 'quality', 'customer', 'product', 'service' and 'design and development'. In addition, some of the terms used in ISO 9001:2008 have been changed; for example:

- 'Product' is replaced by 'Products and Services'
- 'Purchased Product' is replaced by "Externally Provided Processes, Products and Services"
- 'Work Environment' is replaced by 'Environment for the Operation of Processes'



ISO 9001: 2015 NOW REQUIRES ORGANIZATIONS TO IDENTIFY THOSE EXTERNAL AND INTERNAL ISSUES THAT ARE RELEVANT TO ITS 'CONTEXT' AND THAT CAN AFFECT ITS ABILITY TO ACHIEVE THE INTENDED OUTCOME(S) OF ITS MANAGEMENT SYSTEM.

CLAUSE 4
CONTEXT OF THE ORGANIZATION

The 'context' of the organization (sometimes called its business environment) refers to the combination of internal and external factors and conditions that can have an effect on an organization's approach to its products and/or services. As a result, the design and implementation of an organization's QMS will be influenced by its context. (see Figure 3)

An organization's context will include, for example:

- The specific objectives of the organization
- The needs and expectations of its customers and any other relevant 'interested parties'
- The products and services it provides
- The complexity of both the processes that the organization uses and the way in which they interact
- Its size and organizational structure

This is not a completely new concept for QMS, as the Introduction to ISO 9001:2008 (section 0.1 General) includes a reference to the fact that the design and implementation of an organization's QMS is influenced by a similar list of issues and factors.

CONTEXT OF THE ORGANIZATION

Figure 3

CLAUSE 4.1
UNDERSTANDING THE ORGANIZATION AND ITS CONTEXT

ISO 9001:2015 now requires organizations to identify those external and internal issues that are relevant to its 'context' and that can affect its ability to achieve the intended outcome(s) of its management system. The organization must also continue to monitor and review those issues to establish whether any changes to them will affect its QMS, or its purpose. Although many organizations will already be monitoring internal and external issues, this is a new requirement which all will now need to comply with.

Although there is no specific requirement that the identification of these internal and external issues, or their monitoring and review, have to be documented by an organization, it will have to demonstrate that it has been done. In many cases this information could already be available from several different sources. It may form part of an organization's documented business plan or business strategy, for example, or be referenced on the organization's website, in its annual reports to shareholders, or there may even be simply a section in the Management Review minutes dealing with this issue.

CLAUSE 4.2
UNDERSTANDING THE NEEDS AND EXPECTATIONS OF INTERESTED PARTIES

An organization is also required to identify the 'interested parties' that are relevant to its QMS.

An 'interested party' (sometimes referred to as a 'stakeholder') is any person or organization that can affect, be affected by, or perceive themselves to be affected by the decisions or activities of the organization implementing the QMS. These interested parties could include the organization's shareholders, employees, customers, end users, suppliers, regulators, pressure groups, etc.

In order to determine whether an interested party, or its requirements, are relevant to their QMS, the organization must consider whether or not they have an impact on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, or enhance customer satisfaction. Every organization will have its own set of relevant interested parties and these may well change over time. Every interested party will also have its own set of requirements, but not all of these will be relevant to an organization's QMS.

Organisations will need to be able to demonstrate that they have been through an initial process which identifies who their relevant interested parties are, as well as their requirements that are relevant to the organization's QMS. There will also need to be evidence that the organization continues to review whether the relevance of these interested parties and/or their requirements change.

CLAUSE 4.3
DETERMINING THE SCOPE OF THE QUALITY MANAGEMENT SYSTEM

This clause covers some of the requirements in ISO 9001:2008 clauses 1.2 'Application' and 4.2.2 'Quality Manual'. However, whilst there is still a requirement that an organization must establish the scope of its QMS, there is now a specific requirement that when doing so the organization must consider:

a. Its external and internal context issues referred to in clause 4.1

b. The requirements of relevant interested parties referred to in clause 4.2

c. Its products and services

An organization must identify any boundaries and/or limits on the applicability of its QMS. For example, the scope can include the whole of the organization, specific and identified functions of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations. Any physical limitations to the scope of the QMS will also need to be identified. Outsourced functions or processes are considered within the organization's scope.

ISO 9001:2015 no longer makes specific reference to 'exclusions' when determining the applicability of its requirements to an organization's QMS. However, it is recognised that an organization might need to review the applicability of requirements due to the size of the organization, the management model it adopts, the range of the organization's activities, or the nature of the risks and opportunities it encounters.

CLAUSE 4.4
QUALITY MANAGEMENT SYSTEM (QMS) AND ITS PROCESSES

This clause addresses some of the requirements found in ISO 9001:2008 clauses 4.1 'General requirements', 5.4.2 'QMS' planning' and 8.2.3 'Monitoring and measurement of processes'. ISO 9001:2015, however requires the adoption of a process approach when developing, implementing and improving the effectiveness of a QMS.

However, as the achievement of consistent results and outputs is more likely when activities are understood and managed as interrelated processes, ISO 9001:2015 now includes specific requirements necessary for the adoption of a process approach.

This process approach requires an organization to systematically define and manage processes and their interactions so as to achieve the intended results in accordance with both the quality policy and strategic direction of the organization. Although there are similar requirements in ISO 9001:2008 (clause 4.1), ISO 9001:2015 now specifically requires an organization to identify:

- The inputs required and the outputs expected from processes
- The measurements and related performance indicators needed to ensure the effective operation and control of processes
- The assignment of the responsibilities and authorities for processes
- The risks and opportunities associated with processes (see clause 6.1) and the planned and implemented appropriate actions to address them

Operational procedures, work instructions, process diagrams, etc. would be examples of documented information used to support the operation of processes, but individual organizations may have different approaches to this (see clause 7.5, below).

CLAUSE 5
LEADERSHIP

This clause does not just simply cover the same areas of policy, organizational roles, responsibilities and authorities that are present in clause 5 of ISO 9001:2008 – Management Responsibility. There is now an emphasis on 'leadership' rather than just management. Top management are now required to demonstrate a greater direct involvement in the organization's QMS and the removal of the need for a specific 'Management Representative' is partly an attempt to ensure that 'ownership' of an organization's management system is not simply focused on one individual.

CLAUSE 5.1.1
LEADERSHIP AND COMMITMENT TO THE QUALITY MANAGEMENT SYSTEM (QMS)

Top management must be able to demonstrate that they have taken responsibility for emphasizing the importance of conforming to the requirements of their organization's QMS. In addition, they must ensure that the QMS is achieving its intended results and drive continual improvement within their organization.

In those organizations where top management have effectively delegated responsibility for the QMS down to a Management Representative (MR), then under ISO 9001:2015 they will now have to demonstrate much more direct involvement in the QMS. They can still delegate tasks to others, such as the MR, but otherwise the specified requirements must be seen to be undertaken by top management

THERE IS NOW AN EMPHASIS ON LEADERSHIP RATHER THAN JUST MANAGEMENT.

themselves. Top management have to be seen to be 'accountable' for their organization's QMS and to emphasize the importance of effective quality management and conformance with QMS requirements. They must also ensure that QMS requirements are integral to the organization's business processes and be consistent with its overall strategic direction and the context in which it operates.

Several of the ISO 9001:2015 elements that are aimed at top management leadership and commitment require them to 'ensure' that certain activities are undertaken or carried out, this indicates that these tasks maybe delegated to others. However, where there is a specific requirement that top management must be 'taking', 'promoting', 'communicating', 'engaging' and 'supporting' action(s), this indicates that they must be seen to be undertaking these actions themselves.

CLAUSE 5.1.2
CUSTOMER FOCUS

ISO 9001:2015 enhances the current requirement in ISO 9001:2008 clause 5.2 that top management simply ensure that "...customer requirements are determined and are met with the aim of enhancing customer satisfaction". Now they also need to demonstrate that any risks and opportunities are being identified and addressed where they:

- Could potentially have an impact on the organization's ability to supply products and services that conform to customer requirements

In addition, top management have to demonstrate that they maintain a focus on consistently providing products and services that:

- Conform to customer requirements
- Meet applicable statutory and regulatory requirements
- Enhance customer satisfaction

The reference to the need to ensure that the focus on enhancing customer satisfaction is 'maintained' indicates that this is an ongoing requirement. Top management are required to demonstrate leadership and commitment with respect to customer focus 'by ensuring' that these requirements are carried out. This wording suggests that these are tasks which do not have to be directly undertaken by top management and that responsibility for carrying them out may be delegated to other personnel.

CLAUSE 5.2
QUALITY POLICY

Although the requirements in relation to an organization's Quality Policy are broadly the same as those in ISO 9001:2008, there are some new elements. ISO 9001:2015 now requires that an organization's quality policy is appropriate to both its purpose and its 'context' and supports its 'strategic direction'. This means that once the organization has determined its context and the relevant requirements of its interested parties (clauses 4.1 & 2), top management will have to review the quality policy in light of that information.

The Quality Policy itself has to be available as 'documented information' and top management will need to demonstrate that they were involved in its preparation.

There is also a new requirement. The Quality Policy is to be made available to the organization's 'interested parties'. Organisations will need to demonstrate how this is done for both internal and external interested parties. It may be that the Quality Policy is available on the organization's website, for example, but other methods of ensuring its availability could be used.

CLAUSE 5.3
ORGANIZATIONAL ROLES, RESPONSIBILITIES AND AUTHORITIES

Although the requirements in relation to an organization's Quality Policy are broadly the same as those in ISO 9001:2008, there are some new elements. ISO 9001:2015 now requires that an organization's quality policy is appropriate to both its purpose and its 'context' and supports its 'strategic direction'. This means that once the organization has determined its context and the relevant requirements of its interested parties (clauses 4.1 & 2), top management will have to review the quality policy in light of that information.

The Quality Policy itself has to be available as 'documented information' and top management will need to demonstrate that they were involved in its preparation.

There is also a new requirement. The Quality Policy is to be made available to the organization's 'interested parties'. Organisations will need to demonstrate how this is done for both internal and external interested parties. It may be that the Quality Policy is available on the organization's website, for example, but other methods of ensuring its availability could be used.

Again, although this clause covers some of the elements in ISO 9001:2008 clause 5.5 'Responsibility, authority and communication' there are some key changes. There is now a requirement that responsibilities and authorities must not only be assigned and communicated, but also that they have to be understood within the organization. An organization's personnel must, therefore, be advised of their QMS responsibilities and authorities, and a mechanism must be in place to ensure that personnel understand them. In particular, top management need to ensure that specific responsibilities and authorities are assigned, communicated and understood in relation to:

- Ensuring that the QMS conforms to the requirements of ISO 9001:2015
- Ensuring that processes deliver their intended outputs
- Reporting to top management in relation to QMS performance and improvement opportunities

CLAUSE 6

PLANNING FOR THE QUALITY MANAGEMENT SYSTEM (QMS)

Although QMS 'planning' has long been a familiar requirement, ISO 9001:2015 now places a greater emphasis on the planning that an organization does which is integral to its business. An organization is now required to consider both its 'context' and 'interested parties' when planning and implementing its QMS.

CLAUSE 6.1
ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES

This is a new requirement which obliges organizations to identify those risks and opportunities that have the potential to impact (positively or negatively) the operation and performance of their QMS.

Having identified those external and internal issues that are relevant to its context, as well as the needs of interested parties (clauses 4.1 & 2), an organization is required to use that information to determine both the risks and opportunities that need to be addressed to:

- Ensure that its management system can achieve its intended outcome(s)
- Prevent, or reduce, undesired effects
- Achieve improvement

Based on the results of this assessment, organizations then have to:

- Take action to address any risks and opportunities identified
- Integrate and implement these actions into their QMS processes
- Evaluate the effectiveness of the actions taken

Not all of the processes of a QMS represent the same level of risk or opportunity in terms of the organization's ability to meet its objectives. For that reason, ISO 9001:2015 requires that the actions taken to address any risks and opportunities are "...proportionate to the potential impact on the conformity of products and services". The consequences of failures or non-conformities in relation to processes, systems products and/or services, for example, will not be the same for all organizations. So when deciding how to plan and control its QMS, including its component processes and activities, the organization needs to consider both the type and level of risk or opportunity associated with them.

There needs to be evidence that the organization has done this and that it continues to review whether these issues and requirements change. It also needs to demonstrate that the action taken is subsequently reviewed to confirm whether it has been effective or not. Although risks and opportunities have to be determined and addressed, there is no requirement for a formal, documented risk management process, and organizations are free to choose the assessment and evaluation mechanism they consider is most appropriate for them. However, organizations must be able to demonstrate that they have a planned methodology in place that allows them to determine all/any risks and opportunities relevant to the planning and implementation of their QMS.

CLAUSE 6.2
QUALITY OBJECTIVES AND PLANNING TO ACHIEVE THEM

The requirements relating to quality objectives in ISO 9001:2008 clause 5.4 are retained in ISO 9001:2015. However, in addition to the need to establish measurable quality objectives at relevant functions and levels, that are consistent with an organization's quality policy, there are now requirements that must be established for 'relevant processes' and be relevant to the 'enhancement of customer satisfaction'. These changes implied that orgnisations will now have to demonstrate that their quality objectives actually 'add value' and that they have not simply been established in order to meet the bare minimum requirements of ISO 9001:2015.

The requirements relating to the planning needed to achieve quality objectives implied in ISO 9001:2008 are now more explicitly detailed. Organisations are now required to determine:

- What resources will be required to achieve quality objectives
- Who will be responsible for them
- What will be done and when
- How will achievement of the objectives be evaluated

Organisations will need to demonstrate that these "what, when, who and how" elements have been satisfactorily planned, but since an organization has to retain documented information on their quality objectives this should be available in some documented form or other. Organisations will also have to demonstrate that the personnel to whom responsibility for quality objectives has been given are aware of what their responsibilities are and have been given the resources to achieve those objectives.

ISO 9001:2015 NOW PLACES A GREATER EMPHASIS ON THE PLANNING THAT AN ORGANIZATION DOES WHICH IS INTEGRAL TO ITS BUSINESS.

CLAUSE 6.3
PLANNING OF CHANGES

ISO 9001:2015 still contains the key requirement in ISO 9001:2008 clause 5.4.2 (b) that the integrity of an organization's QMS must be maintained when any changes to it are planned and implemented, but also now added further requirements. In addition to a general requirement that all changes to an organization's QMS are "...carried out in a planned manner" this process must include consideration of:

- Why the change is being made and the potential consequences of that change
- Any effects on the integrity of the QMS
- Whether the resources necessary to carry out the change are available
- The allocation or reallocation of related responsibilities and authorities caused by the change

Since ISO 9001:2015 clause 4.4 requires organizations to maintain/retain documented information "...to the extent necessary to support the operation of processes" then the activities related to QMS changes, including consideration of the issues above, will need to be documented. Organisations will need to demonstrate that they have taken these issues into account when making changes to their QMS.

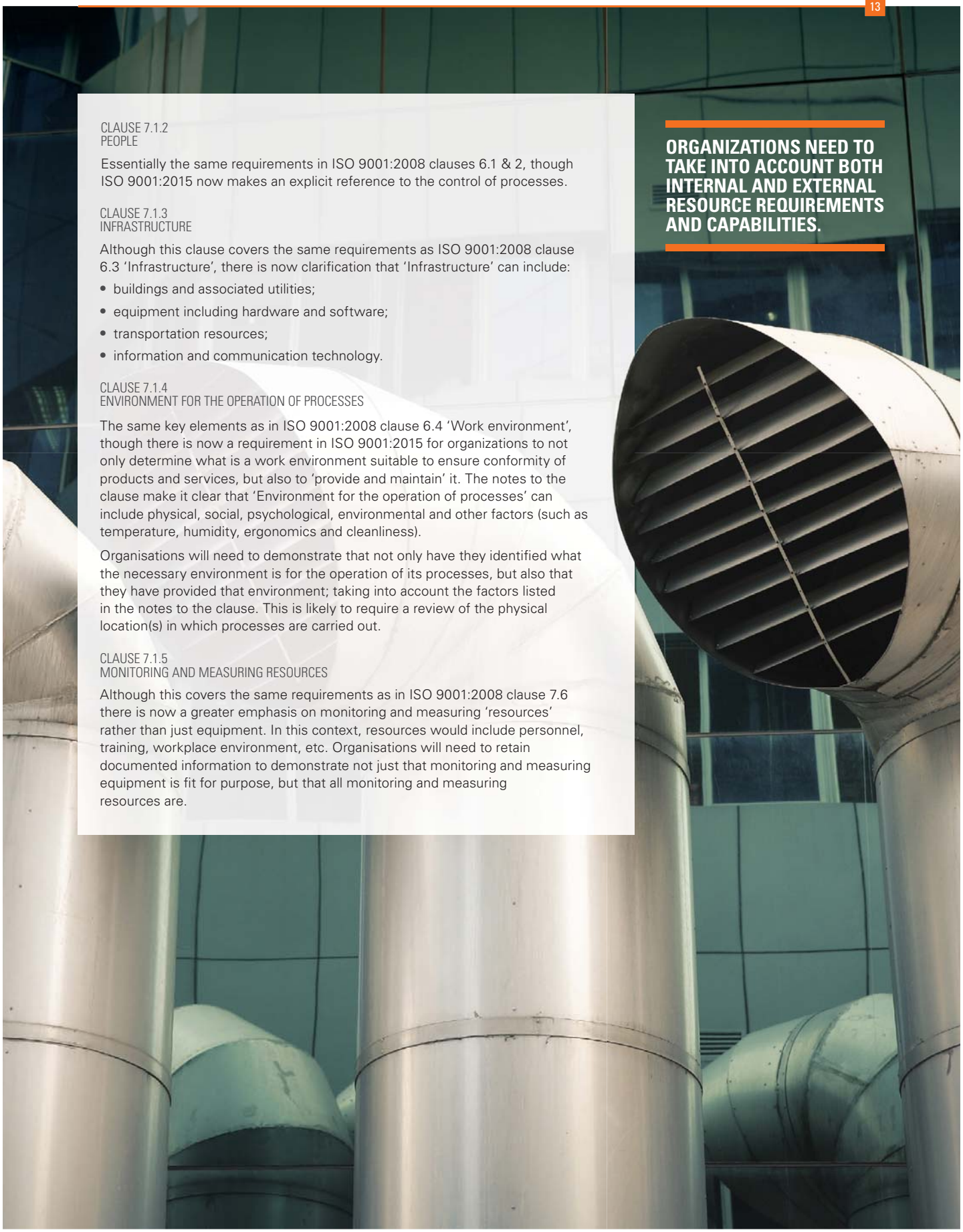
CLAUSE 7
SUPPORT

Having addressed the organization's context, commitment and planning, this clause sets out the QMS requirements relating to the support needed in order to meet the organization's goals.

CLAUSE 7.1
RESOURCES

CLAUSE 7.1.1
GENERAL

Although implicit in ISO 9001:2008 clause 6.1 'Provision of resources', ISO 9001:2015 now makes consideration/evaluation of resource capabilities a specific requirement. Additionally, when identifying the resources needed to establish, implement, maintain and improve its QMS, there is now a requirement that an organization needs to take into account both internal and external resource requirements and capabilities. There is no specific requirement that documented evidence needs to be available to demonstrate this, but organizations will need to demonstrate that both internal and external resource requirements and capabilities are considered.



CLAUSE 7.1.2
PEOPLE

Essentially the same requirements in ISO 9001:2008 clauses 6.1 & 2, though ISO 9001:2015 now makes an explicit reference to the control of processes.

CLAUSE 7.1.3
INFRASTRUCTURE

Although this clause covers the same requirements as ISO 9001:2008 clause 6.3 'Infrastructure', there is now clarification that 'Infrastructure' can include:

- buildings and associated utilities;
- equipment including hardware and software;
- transportation resources;
- information and communication technology.

CLAUSE 7.1.4
ENVIRONMENT FOR THE OPERATION OF PROCESSES

The same key elements as in ISO 9001:2008 clause 6.4 'Work environment', though there is now a requirement in ISO 9001:2015 for organizations to not only determine what is a work environment suitable to ensure conformity of products and services, but also to 'provide and maintain' it. The notes to the clause make it clear that 'Environment for the operation of processes' can include physical, social, psychological, environmental and other factors (such as temperature, humidity, ergonomics and cleanliness).

Organisations will need to demonstrate that not only have they identified what the necessary environment is for the operation of its processes, but also that they have provided that environment; taking into account the factors listed in the notes to the clause. This is likely to require a review of the physical location(s) in which processes are carried out.

CLAUSE 7.1.5
MONITORING AND MEASURING RESOURCES

Although this covers the same requirements as in ISO 9001:2008 clause 7.6 there is now a greater emphasis on monitoring and measuring 'resources' rather than just equipment. In this context, resources would include personnel, training, workplace environment, etc. Organisations will need to retain documented information to demonstrate not just that monitoring and measuring equipment is fit for purpose, but that all monitoring and measuring resources are.

ORGANIZATIONS NEED TO TAKE INTO ACCOUNT BOTH INTERNAL AND EXTERNAL RESOURCE REQUIREMENTS AND CAPABILITIES.

CLAUSE 7.1.6
ORGANIZATIONAL KNOWLEDGE

This is a new requirement which addresses the need for organizations to determine and maintain the knowledge obtained by the organization (including its personnel) to ensure that it can achieve conformity of products and services. The primary requirement is that an organization must establish the knowledge necessary for it to satisfactorily operate the processes it uses and provide products and services which conform to requirements.

The type of 'organization knowledge' that will need to be maintained will vary from one organization to another. It is likely to include knowledge held by competent personnel within the organization that they use to carry out their operational tasks, for example, but it may also include bespoke software needed to run process equipment, internal and/or external product and service standards, technical manuals, intellectual property, etc. The amount or level of organizational knowledge needed may be large or small, depending on an individual organization's activities, processes and circumstances, but the key question is whether the organization has identified the knowledge it needs to have in order to carry out its processes and activities. This knowledge needs to be maintained and made available where and when necessary. It is up to the organization to decide how to do this and there is no specific requirement that this knowledge has to be retained as documented information. Additionally, when planning changes to its QMS or operational activities, an organization is required to assess whether its existing organizational knowledge is sufficient to satisfactorily manage these changes or if it needs to obtain additional knowledge to do so and take steps to get it if necessary.

ORGANIZATIONS NEED TO TAKE INTO ACCOUNT BOTH INTERNAL AND EXTERNAL RESOURCE REQUIREMENTS AND CAPABILITIES.

CLAUSE 7.2
COMPETENCE

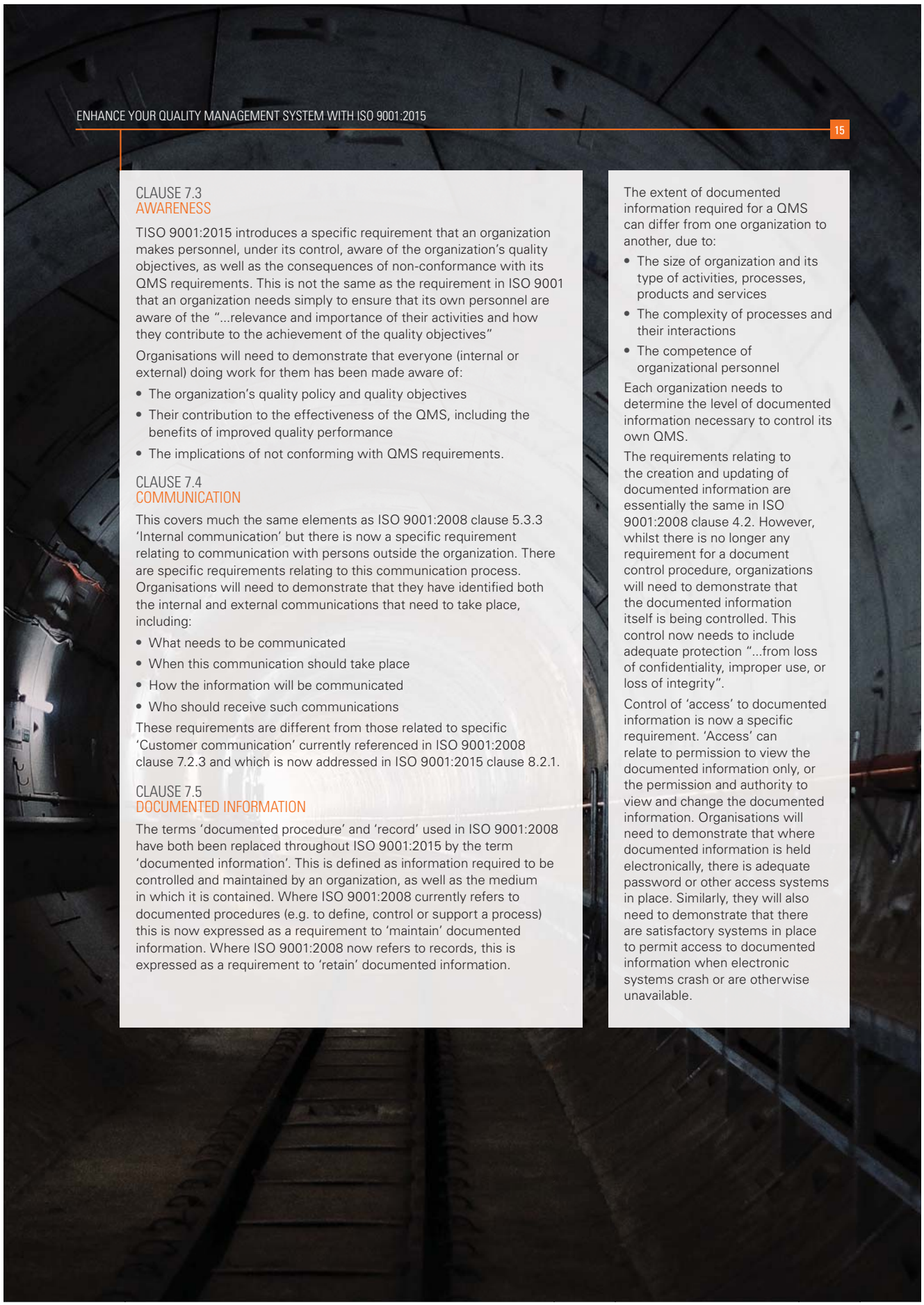
Essentially the same requirements in ISO 9001:2008 clause 6.2 'Human resources', though ISO 9001:2015 now requires organizations to demonstrate that it has determined the competency requirements for personnel and must:

- Ensure that personnel meet those competency requirements
- Take action to ensure that they acquire the identified competence

The organization also needs to demonstrate that any action taken to acquire or maintain competency is subsequently reviewed to establish whether it has been effective in raising personnel competence to the required level(s).

A key addition to the requirements is that they now apply to all/any personnel 'under its control' that affect the organization's performance. This will include any sub-contract/ agency personnel, as well as anyone undertaking outsourced processes and functions (see the reference to the need to communicate competence requirements to external providers in clause 8.4.3 (c) below).

Organisations will need to retain documented information to demonstrate that all personnel under their control are competent. This is different to the current ISO 9001:2008 requirement that organizations must simply maintain appropriate records of "...education, training, skills and experience".



CLAUSE 7.3
AWARENESS

TISO 9001:2015 introduces a specific requirement that an organization makes personnel, under its control, aware of the organization's quality objectives, as well as the consequences of non-conformance with its QMS requirements. This is not the same as the requirement in ISO 9001 that an organization needs simply to ensure that its own personnel are aware of the "...relevance and importance of their activities and how they contribute to the achievement of the quality objectives"

Organisations will need to demonstrate that everyone (internal or external) doing work for them has been made aware of:

- The organization's quality policy and quality objectives
- Their contribution to the effectiveness of the QMS, including the benefits of improved quality performance
- The implications of not conforming with QMS requirements.

CLAUSE 7.4
COMMUNICATION

This covers much the same elements as ISO 9001:2008 clause 5.3.3 'Internal communication' but there is now a specific requirement relating to communication with persons outside the organization. There are specific requirements relating to this communication process. Organisations will need to demonstrate that they have identified both the internal and external communications that need to take place, including:

- What needs to be communicated
- When this communication should take place
- How the information will be communicated
- Who should receive such communications

These requirements are different from those related to specific 'Customer communication' currently referenced in ISO 9001:2008 clause 7.2.3 and which is now addressed in ISO 9001:2015 clause 8.2.1.

CLAUSE 7.5
DOCUMENTED INFORMATION

The terms 'documented procedure' and 'record' used in ISO 9001:2008 have both been replaced throughout ISO 9001:2015 by the term 'documented information'. This is defined as information required to be controlled and maintained by an organization, as well as the medium in which it is contained. Where ISO 9001:2008 currently refers to documented procedures (e.g. to define, control or support a process) this is now expressed as a requirement to 'maintain' documented information. Where ISO 9001:2008 now refers to records, this is expressed as a requirement to 'retain' documented information.

The extent of documented information required for a QMS can differ from one organization to another, due to:

- The size of organization and its type of activities, processes, products and services
- The complexity of processes and their interactions
- The competence of organizational personnel

Each organization needs to determine the level of documented information necessary to control its own QMS.

The requirements relating to the creation and updating of documented information are essentially the same in ISO 9001:2008 clause 4.2. However, whilst there is no longer any requirement for a document control procedure, organizations will need to demonstrate that the documented information itself is being controlled. This control now needs to include adequate protection "...from loss of confidentiality, improper use, or loss of integrity".

Control of 'access' to documented information is now a specific requirement. 'Access' can relate to permission to view the documented information only, or the permission and authority to view and change the documented information. Organisations will need to demonstrate that where documented information is held electronically, there is adequate password or other access systems in place. Similarly, they will also need to demonstrate that there are satisfactory systems in place to permit access to documented information when electronic systems crash or are otherwise unavailable.

CLAUSE 8

OPERATION

This is the clause that addresses the main business activities of the organization implementing its QMS and, in addition to requirements relating to operational planning and control. This is the section in which most QMS-specific requirements are found.

CLAUSE 8.1
OPERATIONAL PLANNING AND CONTROL

Although these requirements are similar to those in ISO 9001:2008 clause 7.1 'Planning of product realisation', there is now a greater emphasis on the control of processes. ISO 9001:2015 introduces a requirement to establish the 'criteria for the processes' and to implement controls 'in accordance with the criteria'. The emphasis is on controlling the processes, so organizations will need to demonstrate that they have planned and implemented the appropriate process criteria:

- Inputs, outputs, resources, controls, criteria, process measurement indicators, etc.

Organisations will need to demonstrate that they have identified criteria for the control of processes and that these controls have been implemented as planned. The processes involved will not only be those necessary to meet requirements for conforming products and services, but also those required to implement any actions needed to address identified risks and opportunities.

Organisations are also required to control not only planned changes to processes (and to process controls), but also to unintended, unplanned changes. Where unintended changes are made, the organization has to demonstrate that it identifies any actual or potential adverse effects and takes action to mitigate them.

An organization is required to retain the documented information necessary to demonstrate that its processes have been carried out as planned and that products and services conform to requirements. This will include information on any unplanned changes, adverse effects and actions taken to address them.

CLAUSE 8.2
REQUIREMENTS FOR PRODUCTS AND SERVICES

CLAUSE 8.2.1
CUSTOMER COMMUNICATION

The requirements in ISO 9001:2015 are very similar to those in ISO 9001:2008 clause 7.2 'Customer-related processes'. However, there is now an additional requirement that organizations must communicate with customers in relation to specific, identified issues. There is also now a requirement that these processes must include, where relevant, communicating with customers in relation to:

- The handling or treatment of customer property
- Specific requirements for contingency actions

Additionally, organizations must also now have in place processes for obtaining 'feedback relating to products and services', including customer complaints. This is different to the current ISO 9001:2008 requirement to simply obtain 'customer feedback'.

Organisations will need to demonstrate that they have a controlled methodology in place for communicating with clients and that these processes are systematically and consistently carried out.

CLAUSE 8.2.2
DETERMINATION OF REQUIREMENTS RELATED TO PRODUCTS AND SERVICES

ISO 9001:2015 now requires organizations to meet the claims for the products and services it offers.

Again, organizations will have to demonstrate that they have a controlled methodology in place for doing so. Equally, organizations will have to be able to show that any claims they make about their products and services can be proved or demonstrated. This may include claims made in direct communication with clients, technical product information, marketing materials, etc.

CLAUSE 8.2.3
REVIEW OF REQUIREMENTS RELATED TO PRODUCTS AND SERVICES

This clause contains very similar requirements in ISO 9001:2008 clauses 7.2.1 & 2, and organizations are still required to retain documented information which describes the results of the review(s).

In the same way, details of changes to requirements and review of those changes has to be retained as documented information.

CLAUSE 8.3
DESIGN AND DEVELOPMENT OF PRODUCTS AND SERVICES

CLAUSE 8.3.1
GENERAL

Organisations are now required simply to establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.

ORGANISATIONS NEED TO DEMONSTRATE A SPECIFIC PROCESS FOR ESTABLISHING THE REQUIREMENTS FOR THE PRODUCTS AND SERVICES IT INTENDS TO OFFER TO CUSTOMERS.

CLAUSE 8.3.2
DESIGN AND DEVELOPMENT PLANNING

ISO 9001:2015 now requires an organization, when determining the necessary stages and controls for design and development, to also consider:

- The nature, duration and complexity of the design and development activities.
- Whether customer and user groups need to be involved in the design and development process and the level of control over the design that they will have.

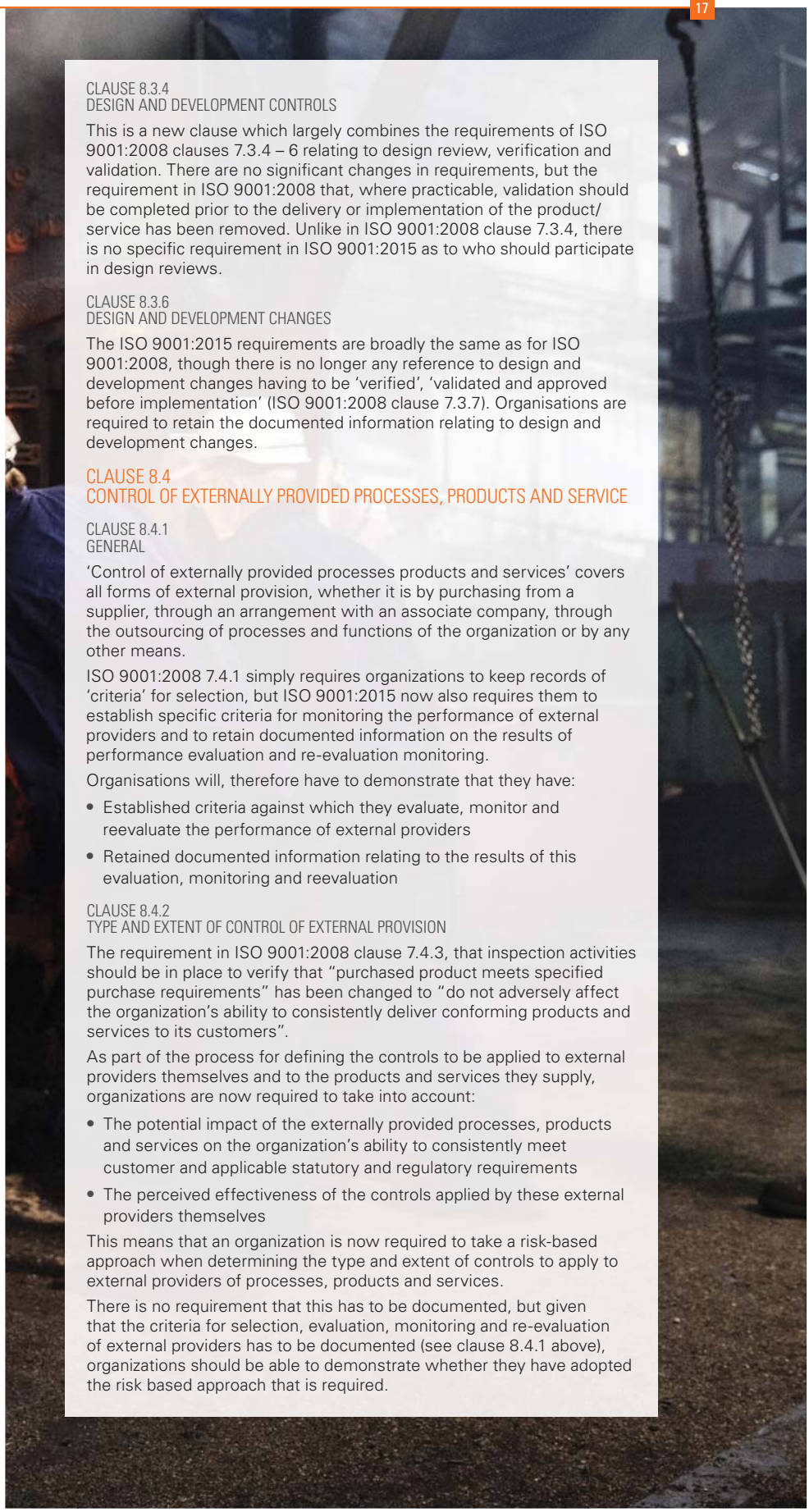
Overall, the requirements are more detailed than those currently specified in ISO 9001:2008 clause 7.3.1 and organizations will need to demonstrate that they have taken into account all the issues highlighted in clause 8.3.2. This will include the retention of all documented information that the organization has identified as necessary to confirm that the design and development requirements have been met.

CLAUSE 8.3.3
DESIGN AND DEVELOPMENT INPUTS

Although the general requirements for design inputs in ISO 9001:2008 are essentially unchanged, ISO 9001:2015 introduces the requirements that an organization must include the following additional design inputs:

- Standards and/or codes of practice that the organization has committed to implement
- The potential consequences of failure due to the nature of the products and services

Organisations will also have to demonstrate that they have a controlled methodology in place for identifying the necessary inputs.



CLAUSE 8.3.4
DESIGN AND DEVELOPMENT CONTROLS

This is a new clause which largely combines the requirements of ISO 9001:2008 clauses 7.3.4 – 6 relating to design review, verification and validation. There are no significant changes in requirements, but the requirement in ISO 9001:2008 that, where practicable, validation should be completed prior to the delivery or implementation of the product/service has been removed. Unlike in ISO 9001:2008 clause 7.3.4, there is no specific requirement in ISO 9001:2015 as to who should participate in design reviews.

CLAUSE 8.3.6
DESIGN AND DEVELOPMENT CHANGES

The ISO 9001:2015 requirements are broadly the same as for ISO 9001:2008, though there is no longer any reference to design and development changes having to be 'verified', 'validated and approved before implementation' (ISO 9001:2008 clause 7.3.7). Organisations are required to retain the documented information relating to design and development changes.

CLAUSE 8.4
CONTROL OF EXTERNALLY PROVIDED PROCESSES, PRODUCTS AND SERVICE

CLAUSE 8.4.1
GENERAL

'Control of externally provided processes products and services' covers all forms of external provision, whether it is by purchasing from a supplier, through an arrangement with an associate company, through the outsourcing of processes and functions of the organization or by any other means.

ISO 9001:2008 7.4.1 simply requires organizations to keep records of 'criteria' for selection, but ISO 9001:2015 now also requires them to establish specific criteria for monitoring the performance of external providers and to retain documented information on the results of performance evaluation and re-evaluation monitoring.

Organisations will, therefore have to demonstrate that they have:

- Established criteria against which they evaluate, monitor and reevaluate the performance of external providers
- Retained documented information relating to the results of this evaluation, monitoring and reevaluation

CLAUSE 8.4.2
TYPE AND EXTENT OF CONTROL OF EXTERNAL PROVISION

The requirement in ISO 9001:2008 clause 7.4.3, that inspection activities should be in place to verify that "purchased product meets specified purchase requirements" has been changed to "do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers".

As part of the process for defining the controls to be applied to external providers themselves and to the products and services they supply, organizations are now required to take into account:

- The potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements
- The perceived effectiveness of the controls applied by these external providers themselves

This means that an organization is now required to take a risk-based approach when determining the type and extent of controls to apply to external providers of processes, products and services.

There is no requirement that this has to be documented, but given that the criteria for selection, evaluation, monitoring and re-evaluation of external providers has to be documented (see clause 8.4.1 above), organizations should be able to demonstrate whether they have adopted the risk based approach that is required.

CLAUSE 8.4.3
INFORMATION FOR EXTERNAL PROVIDERS

The ISO 9001:2015 requirements are very similar to those in ISO 9001:2008 clause 7.4.2, but organizations are now also required to give external providers information about:

- How they will interact with the organization
- How their performance will be monitored and controlled by the organization

There is also an additional requirement that organizations must communicate to external providers any 'competence' requirements which apply to their personnel. This is more than the requirement currently in ISO 9001:2008 clause 7.4.2 (c) that purchasing requirements should include any 'requirements for qualification of personnel'. Organisations will need to demonstrate that the information specified in clause 8.4.3 is communicated to external providers and that the organization ensures the information is adequate before it is communicated to them.

CLAUSE 8.5
PRODUCTION AND SERVICE PROVISION

CLAUSE 8.5.1
CONTROL OF PRODUCTION AND SERVICE PROVISION

The ISO 9001:2015 requirements are very similar to those in ISO 9001:2008 clause 7.4.2, but organizations are now also required to give external providers information about:

- How they will interact with the organization
- How their performance will be monitored and controlled by the organization

There is also an additional requirement that organizations must communicate to external providers any 'competence' requirements which apply to their personnel. This is more than the requirement currently in ISO 9001:2008 clause 7.4.2 (c) that purchasing requirements should include any 'requirements for qualification of personnel'. Organisations will need to demonstrate that the information specified in clause 8.4.3 is communicated to external providers and that the organization ensures the information is adequate before it is communicated to them.

Although the requirements in ISO 9001:2015 are essentially a combination of those in clauses 7.5.1 & 2 in ISO 9001:2008, organizations will now have to demonstrate that controls have been implemented in relation to:

- The availability of documented product/service/process information
- Defined process criteria
- Personnel competence
- The suitability of infrastructure, environment and resources

A key addition is that ISO 9001:2015 now specifically requires organizations to maintain documented information which defines:

- The characteristics of the products to be produced, services to be provided, or activities to be performed
- The results to be achieved

CLAUSE 8.5.2
IDENTIFICATION AND TRACEABILITY

Again, these requirements are very similar to those in ISO 9001:2008 clause 7.5.3, but the emphasis is now on 'outputs' rather than products. These 'outputs' are the results of any activities which are ready for delivery to the organization's customer, or to an internal customer (e.g. receiver of the inputs to the next process).

CLAUSE 8.5.3
PROPERTY BELONGING TO CUSTOMERS OR EXTERNAL PROVIDERS

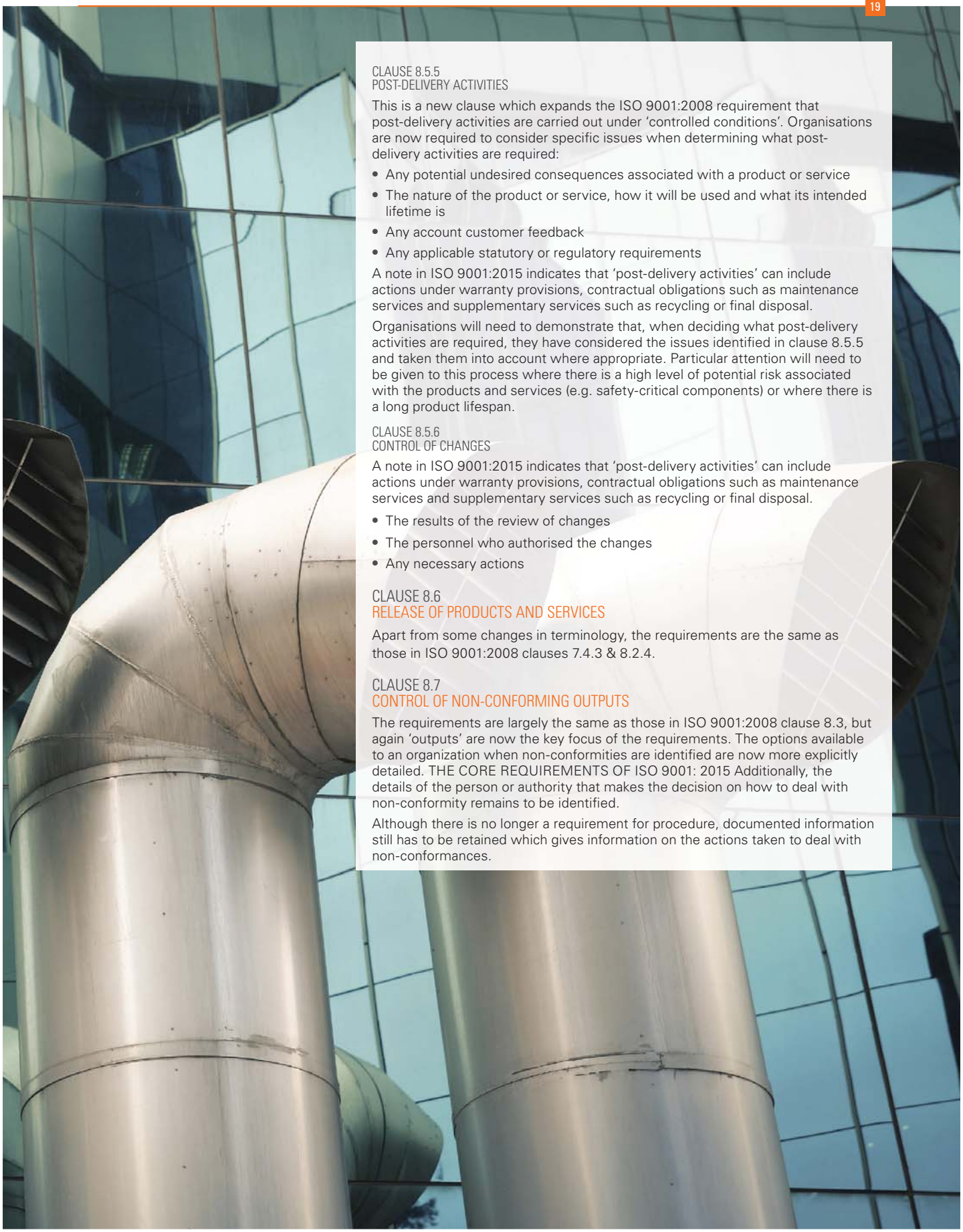
These requirements are broadly in line with those in ISO 9001:2008 clause 7.5.4, but they now also cover property belonging to any external providers used by an organization in its own products and services.

A note now makes it clear that the definition of customer property has been widened to specify that it can include material, components, tools and equipment, customer premises, intellectual property and personal data.

CLAUSE 8.5.4
PRESERVATION

These requirements are almost the same as those in ISO 9001:2008 clause 7.5.5, but again the emphasis now is on 'process outputs' rather than product. A note in ISO 9001:2015 indicates that 'preservation' can include identification, handling, packaging, storage, contamination control, transmission or transportation, as well as protection.

The inclusion of 'transmission' may be an issue where an organization produces and circulates data or other information electronically as part of a product or service. In such cases, organizations will need to demonstrate that the data transmission protection systems they have adopted reflect the risk of loss or security breach identified by the organization.



CLAUSE 8.5.5
POST-DELIVERY ACTIVITIES

This is a new clause which expands the ISO 9001:2008 requirement that post-delivery activities are carried out under 'controlled conditions'. Organisations are now required to consider specific issues when determining what post-delivery activities are required:

- Any potential undesired consequences associated with a product or service
- The nature of the product or service, how it will be used and what its intended lifetime is
- Any account customer feedback
- Any applicable statutory or regulatory requirements

A note in ISO 9001:2015 indicates that 'post-delivery activities' can include actions under warranty provisions, contractual obligations such as maintenance services and supplementary services such as recycling or final disposal.

Organisations will need to demonstrate that, when deciding what post-delivery activities are required, they have considered the issues identified in clause 8.5.5 and taken them into account where appropriate. Particular attention will need to be given to this process where there is a high level of potential risk associated with the products and services (e.g. safety-critical components) or where there is a long product lifespan.

CLAUSE 8.5.6
CONTROL OF CHANGES

A note in ISO 9001:2015 indicates that 'post-delivery activities' can include actions under warranty provisions, contractual obligations such as maintenance services and supplementary services such as recycling or final disposal.

- The results of the review of changes
- The personnel who authorised the changes
- Any necessary actions

CLAUSE 8.6
RELEASE OF PRODUCTS AND SERVICES

Apart from some changes in terminology, the requirements are the same as those in ISO 9001:2008 clauses 7.4.3 & 8.2.4.

CLAUSE 8.7
CONTROL OF NON-CONFORMING OUTPUTS

The requirements are largely the same as those in ISO 9001:2008 clause 8.3, but again 'outputs' are now the key focus of the requirements. The options available to an organization when non-conformities are identified are now more explicitly detailed. THE CORE REQUIREMENTS OF ISO 9001: 2015 Additionally, the details of the person or authority that makes the decision on how to deal with non-conformity remains to be identified.

Although there is no longer a requirement for procedure, documented information still has to be retained which gives information on the actions taken to deal with non-conformances.

CLAUSE 9

PERFORMANCE EVALUATION

This is the clause that addresses the main business activities of the organization implementing its QMS and, in addition to requirements relating to operational planning and control. This is the section in which most QMS-specific requirements are found.

CLAUSE 9.1
MONITORING, MEASUREMENT, ANALYSIS AND EVALUATION

CLAUSE 9.1.1
GENERAL

The current requirement in ISO 9001:2008 clause 8.1 stating that an organization has to plan and implement the necessary "monitoring, measurement, analysis and improvement processes" has been replaced by the requirement that the organization identifies the 'what' 'how' and 'when' of the monitoring and measurement:

- What needs to be monitored and measured
- The methods for monitoring, measurement, analysis and evaluation, as applicable, that are necessary to ensure valid results when the monitoring and measuring shall be performed
- When the results from monitoring and measurement shall be analysed and evaluated

Organisations will also be required to retain documented information as evidence of the results of monitoring and measurement activities.

CLAUSE 9.1.2
CUSTOMER SATISFACTION

The current requirement in ISO 9001:2008 clause 8.1 stating that an organization has to plan and implement the necessary "monitoring, measurement, analysis and improvement processes" has been replaced by the requirement that the organization identifies the 'what' 'how' and 'when' of the monitoring and measurement:

- What needs to be monitored and measured
- The methods for monitoring, measurement, analysis and evaluation, as applicable, that are necessary to ensure valid results when the monitoring and measuring shall be performed
- When the results from monitoring and measurement shall be analysed and evaluated

Organisations will also be required to retain documented information as evidence of the results of monitoring and measurement activities.

ISO 9001:2015 now requires organizations to monitor information relating to the degree to which their needs and expectations have been fulfilled. There is no specific requirement that this information has to be documented, but an organization has to show how it does and what it does with the information that it collects.

A note in ISO 9001:2015 makes it clear that information related to customer views or perceptions can include customer satisfaction or opinion surveys, customer data on delivered products or services quality, market-share analysis, compliments, warranty claims, etc.

CLAUSE 9.1.3
ANALYSIS AND EVALUATION

Although the ISO 9001:2015 requirements are similar to those in ISO 9001:2008 clause 8.4, there are now explicit requirements relating to how the analysis and evaluation of data must be used. Organisations now need to demonstrate 'evaluation' as well as analysis of data (from measurement, monitoring or other sources) and there has to be evidence of data analysis.

Although there is no specific requirement that this analysis and evaluation has to be documented, evidence of what the organization is doing in terms of data analysis and evaluation should be available.

CLAUSE 9.2
INTERNAL AUDIT

The requirements are largely unchanged from those in ISO 9001:2008, but ISO 9001:2015 now requires organizations to demonstrate that when planning an audit programme, they have taken into consideration:

- Any changes which have taken place that impact on the organization

Additionally, there is now a specific requirement that the results of audits are reported to the relevant management within an organization.

Although a documented procedure is no longer required, organizations must retain documented information as evidence of the implementation of the audit programme and the audit results.

CLAUSE 9.3
MANAGEMENT REVIEW

The key requirements of the Management Review process currently in ISO 9001:2008 clause 5.6 remain, but organizations now also need to demonstrate that the 'inputs' to its Management Review include:

- Changes in external and internal issues relevant to both the organization's QMS and to its strategic direction
- Effectiveness of actions taken to address any risks and/or opportunities
- Confirmation of ongoing QMS alignment with the strategic direction of the organization

The new ISO 9001:2015 requirements relating to organizational context and actions to address risks and opportunities are reflected to the Management Review inputs. Organisations will need to demonstrate that these broader organizational issues are integrated into the review process. The limited focus of the current ISO 9001:2008 input requirements will no longer be sufficient and the organization will need to demonstrate that its Management Review deals with how its overall QMS performance is relevant to its strategic direction and organizational environment.

Organisations are required to retain documented information as evidence of the results of Management Review.

CLAUSE 10

IMPROVEMENT

CLAUSE 10.1
GENERAL

This is a new section which emphasizes the general need to improve processes, products and services, as well as QMS results, in order to meet customer requirements and enhance customer satisfaction. Organisations will need to demonstrate that they actively look for opportunities to improve their processes, products and services, as well as the performance of their QMS.

CLAUSE 10.2
NON-CONFORMITY AND CORRECTIVE ACTION

There is, however, now an additional requirement for organizations to address the 'consequences' of non-conformities, which is recognition that not all of its processes and/or activities will represent the same level of risk in terms of the organization's ability to meet its objectives. For that reason, the consequences of failures or non-conformities in relation to processes, systems products and/ or services will not be the same for all organizations. When deciding how to deal with the consequences of non-conformities (including its component processes and activities) organizations will need to demonstrate that they consider both the type and level of risk associated with them.

There is also a new requirement to determine whether any identified non-conformity could also exist elsewhere within the organization's processes, products, services and or systems, or whether they could potentially happen elsewhere. This covers some of the requirements previously included under Preventive Action.

Although a documented procedure is no longer required, organizations are required to retain documented information which identifies the nature of any non-conformities, the subsequent action(s) taken and the results of any corrective action.

CLAUSE 10.3
CONTINUAL IMPROVEMENT

The requirements are largely the same as those in ISO 9001:2008 (clauses 4.1 & 8.5.1), but organizations now also need to demonstrate that they are using the results from their analysis, evaluation and review processes to identify any needs which must be addressed and opportunities for improvement.

CONCLUSION

It is important to note that despite the changes in structure and terminology, this does not mean that an organization is now required to get rid of all its existing manuals and procedures. An organization's existing operational procedures, work instructions, flow charts, process maps, etc. are all examples of documented information and it does not need to remove its current Quality Manual or documented procedures. If an organization wishes to retain these then they can do so. Similarly, organizations do not have to re-structure, re-name or re-number their existing manuals or procedures just to bring them in line with the clause structure in ISO 9001:2015.

In many cases, organizations that have had a QMS in place for several years will have grown accustomed to using their existing documentation and the process security that it brings. There is no reason why they should remove or replace it if they believe it is effective. The key issue for any organization will be ensuring that it meets all the requirements in ISO 9001:2015. The QMS structure or documentation it uses will be irrelevant provided that it does so.

The implications for individual organizations will vary, depending on the degree to which their own QMS already covers the new or revised requirements. For that reason, it would be sensible for each organization, to evaluate the amount of work that they are likely to need to undertake in order to be compliant with these revised requirements. In addition to consideration of the QMS requirements themselves. This evaluation will need to include consideration of the level of training (or re-skilling) that may be required of an organization's personnel.

Any organization looking for a good starting point for adopting the changes, would do well to consider those key organizational elements which are taken from Annex SL and introduced within ISO 9001:2015, by identifying:

- The organization's context
- Its interested parties
- Risks and opportunities relevant to its QMS

Organisations should also give consideration as to whether their existing QMS contains and provides the documented information that is likely to be required.

SGS SOLUTIONS FOR A SMOOTH TRANSITION

As the world's leading certification body and a professional learning and development organization, we offer you a variety of solutions during the transition process.

ISO 9001:2015 COURSES:

- ISO 9001:2015 – Quality Management Systems - Transition Course
- ISO 9001:2015 – Quality Management Systems - Lead Auditor Course (IRCA Approved CPD)
- ISO 9001: 2015 – Quality Management Systems - Internal Auditor Course (IRCA Approved CPD)
- ISO 9001:2015 – Quality Management Systems - Foundation Course (IRCA Approved CPD)

ANNEX SL (IRCA APPROVED CPD)

We help you understand the high-level structure of the new framework and how integration with other management system standards is becoming more efficient.

RISK-BASED THINKING

This course covers the principals that support the identification of risk and opportunities and the different techniques/methodologies needed to address them.

EMPOWERING LEADERSHIP

A training workshop designed to address the required leadership skills of those operating in Quality, Environmental and Health and Safety roles in line with the evolution of MSS within the Annex SL Framework and their related commercial impacts.

GAP ANALYSIS

Our experts can carry out a gap analysis against the new requirements to make your transition smooth and transparent. This provides your organization with structured assistance by highlighting the extent that your existing systems and controls cover the requirements of ISO 9001:2015 and by identifying an implementation action plan where you need it.

ISO 9001:2015 CERTIFICATION

SGS will, of course, now be offering ISO 9001:2015 certification to both new and existing clients.

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sustainabledevelopment@sgs.com

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WHEN YOU NEED TO BE SURE

SGS

HOW CAN YOU PREPARE FOR ISO 9001:2015?

ENHANCE YOUR TRANSITION WITH THIS READINESS CHECKLIST

BE THE BENCHMARK

SGS

"THE TRANSITION MAY BE MORE STRAIGHT FORWARD THAN YOU THINK"

Deborah Cox, D&D Rail Ltd

Feedback from customers that have completed their ISO 9001:2015 transition audit with SGS indicates that, for many, they were much closer to meeting the requirements of the new standard than they had initially thought. As a result of this feedback, we have developed a Readiness Checklist to outline the changes contained in ISO 9001:2015. The checklist has been designed to help you understand what is required and to highlight the areas where your business activities may already comply. Working through the Readiness Checklist will provide you with valuable insight and guidance on how you can begin your transition. It is important to note, however, that the Readiness Checklist cannot count as evidence for your transition audit, as our auditors will have to confirm compliance with the standard during your transition audit visit. – Deborah Cox, D&D Rail Ltd
Read the full case study at www.sgs.com/DandDRail

HOW DOES THE CHECKLIST WORK?

READY

This indicates that you feel you are ready to demonstrate this, and you should look to transition during your next visit from SGS.

NEARLY READY

This indicates that, with guidance or support on this matter, you would be able to demonstrate this. We would recommend looking to transition during your next SGS visit.

WORK TO DO

This option means that you will need further preparation for your audit, or perhaps even training with the SGS Academy.
You can find the relevant next steps at the end of the checklist, where you should have a much better idea on how close you are to transitioning.

CLAUSE 4 – CONTEXT OF THE ORGANIZATION

The 'context' of the organization (sometimes called its business or organizational environment) refers to the combination of internal and external factors and conditions that can have an effect on your organization's approach to its products, services and investments.

4. CONTEXT OF THE ORGANIZATION			
Have you considered	READY	NEARLY READY	WORK TO DO
The external and internal context issues?			
Products and services of your organization?			
Boundaries and/or limits on the applicability of your QMS?			
Identifying, monitoring and reviewing the relevant internal and external issues of your organization to establish whether the impact of any changes to them will affect your QMS?			
Identifying the 'interested parties' that are relevant to your QMS?			
Identifying what requirements these interested parties themselves have, which are relevant to your organization's QMS?			
Continually monitoring and reviewing these interested parties?			
Adopting a process approach when developing, implementing and improving the effectiveness of your QMS?			
Establishing the scope of your QMS?			

CLAUSE 5 – LEADERSHIP

Your top management is now required to demonstrate a greater direct involvement in your organization's QMS. The removal of the need for a specific 'Management Representative' is partly an attempt to ensure that 'ownership' of your organization's QMS is not simply focused on an individual person. Although the requirements in relation to your organization's Quality Policy are broadly the same as the previous version, there are some new elements that now require that your organization's quality policy is appropriate to both its purpose and its 'context'.

5. LEADERSHIP AND WORKER PARTICIPATION			
Questions	READY	NEARLY READY	WORK TO DO
Is top management involved in the QMS preparation and continued review?			
Do they ensure that the Quality Policy is communicated within your organization and to relevant parties?			
Are responsibilities and authorities assigned and communicated by top management?			
Are these understood within your organization?			
Can top management demonstrate that they			
Have taken responsibility for emphasising the importance of conforming to the requirements of your QMS?			
Ensure that the QMS is achieving its intended results?			
Drive continual improvement within your organization?			
Promote the use of risk based thinking and customer focus?			

CLAUSE 6 – PLANNING

Your organization is now required to consider both its context and interested parties when planning and implementing the QMS. You are required to identify those risks and opportunities that have the potential to impact (positively or negatively) the operation and performance of your QMS. Although risks and opportunities have to be determined and addressed, there is no requirement for a formal, documented risk management process and you are free to choose the assessment and evaluation mechanism you consider most appropriate.

6. PLANNING			
Questions	READY	NEARLY READY	WORK TO DO
Have you established measurable quality objectives at relevant functions and levels?			
Are they consistent with your organization's quality policy?			
Are they established for relevant processes and are they relevant to the enhancement of customer satisfaction?			
Is your organization's QMS maintained when any changes to it are planned and implemented?			
When carrying out the changes, is consideration taken into account of why the change is being made and any potential consequence of those changes?			
Have you identified that there are resources necessary to carry out the changes?			

CLAUSE 7 – SUPPORT

You now need to consider both internal and external resource requirements and capabilities to be able to meet customer, and statutory and regulatory requirements. Greater emphasis on monitoring and measuring 'resources' rather than simply equipment is now required.

7. SUPPORT			
Questions	READY	NEARLY READY	WORK TO DO
Have you determined and provided the resources needed for the establishment, implementation, maintenance and continual improvement of the EnMS and energy performance?			
Have you determined and maintained the knowledge obtained by your organization to ensure that your organization can control your energy performance and EnMS?			
There is now an additional requirement for you to address the consequences of non-conformities, which is a recognition that not all its processes and/or activities will represent the same level of risk in terms of your organization's ability to meet its objectives.			
Questions			
Have you retained documented information to demonstrate that all personnel under your control are competent?			
Are all personnel under your control aware both of your organization's quality objectives as well as the consequences of nonconformance with your QMS requirements?			
Questions			
What needs to be communicated?			
When it needs communicating?			
How will it be communicated?			
Who will receive such communications?			

KEY NOTES

The terms documented procedure and record have both been replaced by the term documented information. You will need to determine the level of documented information necessary to control your EnMS. Control of access to documented information is now a specific requirement and can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

CLAUSE 8 – OPERATIONS

You are now required to manage SEUs and implement action plans. It allows energy management (SEU) and energy performance improvement (action plans) to be linked to your organization's business processes (competency, training, communication, operational controls, etc.).

8. OPERATIONS			
Can you	READY	NEARLY READY	WORK TO DO
Demonstrate that you have specific processes in place for establishing the requirements for the products and services you intend to offer to customers?			
Substantiate any claims you make in respect to the products and services you offer?			
Show a designed process where requirements for your products and services have not been established or defined, to the extent that enables product/service provision to take place?			
You are now required to include 'information derived from previous similar designs' as design inputs, as well as the potential consequences of failure due to the nature of your products and services, and any standard(s) or code(s) of practice that you are committed to implement.			
Questions			
Have you taken a risk-based approach when determining the type and extent of controls to apply to your external providers of processes, products and service?			
Do you communicate to your external providers any 'competence' requirements which will apply to their personnel?			
For identification and traceability, the emphasis is now on 'process outputs' rather than products and are a result of any activities which are ready for delivery to your customer or to your internal customers.			
Questions			
Can you identify, verify, protect and safeguard property belonging to any customer and/or external providers used by your organization?			
Do you retain documented information on the release of products and services, verifying that they have met customer requirements and are traceable to the person(s) authorising the release?			

KEY NOTES

Process outputs that do not conform to their requirements must be identified and controlled. You will have to retain documented information describing the nonconformity, the actions taken, any concessions obtained and identify the authority who decided the course of action taken.

CLAUSE 9 – PERFORMANCE EVALUATION

You will find requirements have been better defined in respect to when monitoring and measuring shall be performed and when the results shall be analysed and evaluated.

9. PERFORMANCE EVALUATION			
Question	READY	NEARLY READY	WORK TO DO
Can you demonstrate that you have sought out information relating to how customers view your organization, as well as your products and services?			
There is no fundamental change in the approach to internal audits. However, you are now required to report the 'results of audits' to the relevant management within your organization.			

KEY NOTES

The key requirements of the Management Review process remain as before but additional requirements relating to changes in external and internal issues relevant to your QMS, external provider and relevant interested party issues, and the effectiveness of actions taken to address any risks and/or opportunities have been included as inputs.

CLAUSE 10 – IMPROVEMENTS

This is a new section that emphasizes the general need to improve processes, products and services, as well as QMS results, in order to meet customer requirements and enhance customer satisfaction.

10. IMPROVEMENTS			
Question	READY	NEARLY READY	WORK TO DO
Can you demonstrate that you are actively looking for opportunities to improve the performance of your EnMS?			
There is now an additional requirement for you to address the consequences of non-conformities, which is a recognition that not all its processes and/or activities will represent the same level of risk in terms of your organization's ability to meet its objectives.			
Can you identify whether any non-conformity could also exist elsewhere within your facilities, equipment, systems and processes or whether they could potentially happen elsewhere?			
Can you demonstrate that you are continually improving the adequacy, suitability and effectiveness of your EnMS?			

GETTING STARTED

Hopefully this ISO 9001:2015 Readiness Checklist has helped you to understand more about the changes of the new standard, and what is required from you to achieve a successful transition. Below is an indication of what your results indicate in terms of your next step.

IF THE MAJORITY (OR ALL YOUR ANSWERS ARE READY (WITH NEARLY READY MAKING UP THE MINORITY):	IF MAJORITY OF YOUR ANSWERS ARE NEARLY READY, WITH A MIX OF READY AND WORK TO DO MAKING UP THE MINORITY:	IF MAJORITY OF YOUR ANSWERS WORK TO DO, WITH THE MINORITY SHOWING EITHER READY OR NEARLY READY:
Congratulations! You are ready to book your transition audit with SGS. This can be done by emailing sustainable-development@sgs.com	In this instance, your organization would benefit from a gap analysis to help identify the areas that need to be addressed and to provide practical ways in which this can be achieved. To do this, please contact your SGS Auditor or local office directly.	It seems there are still some areas of the new standard that you are not quite up-to-date with yet, but this can be resolved in a variety of ways. • SGS Academy – SGS Academy hosts a variety of transition training courses. Aimed at organizations already certified to the previous version of ISO 9001, the transition courses last for one day and offer a time-efficient way of understanding the recent changes. • SGS Product Expert Consultation – Another way to increase your knowledge of the new standard is to schedule a consultation with one of our product experts over the phone. • Gap Analysis Audit – A gap analysis is a great method of identifying areas that need attention and understanding the ways in which they can be addressed.

RESOURCE MATERIAL TO HELP SUPPORT YOUR TRANSITION

The decision to book your transition audit should be a simple one, however aspects surrounding the publication of a new standard can seem daunting. SGS is committed to make the transition as easy as possible for our customers, and provide continuously updated information and resources on our website.

CONTACT SGS

For an optimal transition towards ISO 9001:2015 contact:


sustainable-development@sgs.com


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