

# GUIDE TO THE INTERPRETATION AND APPLICATION OF THE ISO 9001:2015 STANDARD FOR THE CONSULTING ENGINEERING INDUSTRY



Fédération Internationale des Ingénieurs-Conseils  
International Federation of Consulting Engineers  
Internationale Vereinigung Beratender Ingenieure  
Federación Internacional de Ingenieros Consultores





**FIDIC** is the international federation of national Member Associations of consulting engineers.

**F**IDIC was founded in 1913 by three national associations of consulting engineers within Europe. The objectives of forming the Federation were to promote in common the professional interests of the Member Associations and to disseminate information of interest to their members. Today, FIDIC membership covers some 90 countries from all parts of the globe encompassing most of the private practice consulting engineers.

**F**IDIC is charged with promoting and implementing the consulting engineering industry's strategic goals on behalf of Member Associations. Its strategic objectives are to: represent world-wide the majority of firms providing technology-based intellectual services for the built and natural environment; assist members with issues relating to business practice; define and actively promote conformance to a code of ethics; enhance the image of consulting engineers as leaders and wealth creators in society; promote the commitment to environmental sustainability; support and promote young professionals as future leaders.

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**F**IDIC organises an extensive programme of seminars, conferences, capacity building workshops, and training courses.

**F**IDIC aims to maintain high ethical and professional standards throughout the consulting engineering industry through the exchange of views and information, with discussion of problems of mutual concern among Member Associations and representatives of the multilateral development banks and other international financial institutions.

**F**IDIC publications and details about training courses and conferences are available from the Secretariat in Geneva, Switzerland. Specific activities are detailed in an annual business plan and the FIDIC website, [www.fidic.org](http://www.fidic.org), gives extensive background information.

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## PREFACE

The primary purpose of this Guide to the Interpretation and Application of the ISO 9001:2015 Standard for the Consulting Engineering Industry (hereafter: the “Guide”) is to provide advice appropriate to our industry for applying ISO 9001:2015 requirements in a Quality Management System (QMS). The Guide aims to facilitate the understanding of the ISO 9001:2015 International Standard by members of our industry.

This Guide is intended to be read in conjunction with ISO 9001:2015.

In 1997 FIDIC and EFCA issued the first Guide. The Guide was updated in 2001 to reflect requirements of ISO 9001:2000. Substantial changes were made from the manufacturing-oriented 1994 edition of the Standard with its 20 “quality elements” to the “process-based” 2000 edition.

For the ISO 9001:2008 revision, no updated Guide was issued. Minor amendments included the question of assessing the effect of training (rather than the training provider), the generalization of the notion of customer property (beyond customer-supplied product), and the retention of responsibility for outsourced processes.

A fundamental review of the ISO 9001 Standard was conducted between 2009 and 2015, resulting in the publication of ISO 9001:2015. This Guide reflects requirements of ISO 9001:2015. The new standard broadens the organization’s view to consider the context of the organization and the needs and expectations of relevant interested parties when determining the scope of the QMS. The concept of risk-based thinking is applied throughout the standard to a much stronger extent than in previous revisions and replaces the concept of preventive action. Taking account of an increasingly digitised world, the standard replaces the terms “documents” and “records” with the term “documented information”. Overall the structure and terminology of standard are aligned to other management system standards such as ISO 14001:2015 through common text defined in a high level structure issued by the International Organization for Standardization (ISO/ IEC Directives Part 1, Annex SL).

The use of the common high level structure facilitates understanding of requirements among different ISO management system standards. Annex SL is not designed as a model for the structure or terminology used in documenting an organization’s management system. This Guide encourages consulting engineering firms to adapt their management system so that it meets both their practical needs and the requirements of relevant management system standards. Depending on client requirements firms might choose either to fully integrate quality, environmental and health & safety management processes or, where appropriate, to separate some processes to facilitate the preparation of project-based management plans for submission to clients.

This second update of the Guide was prepared by FIDIC and EFCA’s Task Force on Quality Management both under the chairmanship of Walter Painsi (Austria) with significant contributions by Sonja de Klerk (South Africa), Martin Hohberg (Switzerland), Diane Baguley (New Zealand) and Alex Ezrakhovich (Australia). FIDIC would also like to thank Margaret Walker, MWCAM Ltd, for her editing services.

FIDIC and EFCA would be pleased to receive feedback from the users of the Guide on its usefulness and areas for improvement. Comments and suggestions for improvements should be forwarded to the FIDIC or EFCA secretariats.

# 1 INTRODUCTION

## 1.1 Purpose of the Guide

This Guide seeks to assist firms in the consulting engineering industry in choosing and determining how best to apply the ISO 9001:2015 standard to their existing management system.

The Guide consists of four main sections:

1. Introduction
2. Application of ISO 9001:2015 to consulting engineering services
3. Interpretation of ISO 9001:2015 requirements for the consulting engineering industry
4. Bibliography - References and further reading

The Guide should be read in conjunction with the ISO 9000 family of standards. For more information on the ISO 9000 family of standards and the related guidelines, please refer to Annex B of ISO 9001:2015.

The Guide covers all services provided by a consulting engineering firm and is not limited to design services only. Even without full compliance with ISO 9001:2015 a firm can expect significant benefits from its application in terms of internal organization, ease of induction of new employees and so forth.

Like its predecessors ISO 9001:2015 is intended for contractual situations between an organization and its clients, for example the engineering firm and its clients, the public and private sectors. ISO 9001:2015 does not require

that a QMS be independently audited by a certification body. However, in many cases ISO 9001 certification is an expected requirement by industry and clients.

Where a firm has not yet established a formal QMS, it is important to realise that their management system may already address many requirements of ISO 9001:2015.

Apart from 3rd Party Audits for certification purposes, an engineering firm may be audited by its (prospective) clients (i.e. a 2nd Party Audit) or 3rd Party Audits on behalf of a client. Insurance companies may – prior to granting coverage such as professional indemnity and public liability - reserve the right for their own on-site inspections. Maintaining a certifiable QMS in conformity with ISO 9001:2015 is a worthwhile investment.

If a certification body is chosen, the firm needs to undertake an evaluation of suitably competent certification bodies and their auditors, who understand the consulting engineering business. Auditors also need to be able to align the way the firm system is operating with the requirements of ISO 9001:2015 relevant to consulting engineering. Evaluation of prospective 3rd Party Auditors may for example include review of their Curriculum Vitae, professional registration(s) if applicable and personal interviews. Accreditation of the certification body may be a prerequisite. For further information refer to the document issued by the International Accreditation Forum (IAF), *Expected Outcomes for Accredited Certification to ISO 9001* at [www.iaf.nu](http://www.iaf.nu)

## 1.2 Main Changes from ISO 9001:2008 to the new ISO 9001:2015

Due to the introduction of Annex SL (high level structure) the former structure of ISO 9001 was changed and common core text which is mandated for ISO management systems standards was incorporated.

Several definitions have been changed to align them with the Annex SL (high level

structure) but there is no requirement to change the terms used by an organization to comply with the requirements of the revised ISO 9001. Terms and definitions are provided in ISO 9000:2015 and are also available by searching for 9000 under terms and definitions on the ISO on-line browsing platform at [www.iso.org/obp](http://www.iso.org/obp) and the IEC Electropedia at [www.electropedia.org](http://www.electropedia.org)

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Other changes from the 2008 edition are:

- **Process approach:** As stated in the ISO Quality Management Principles, “consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system” (see [www.iso.org](http://www.iso.org)). The standard is now explicit in requiring the adoption of a process approach when developing, implementing and improving the effectiveness of a QMS, to enhance customer satisfaction by meeting customer requirements. Guidance on the process approach is available in <https://committee.iso.org/tc176sc2>
- **Context of the organization:** Introduction of the requirement for “Context of the organization” places considerable emphasis on understanding the organization’s environment and the status of its QMS as a basis for considering opportunities and risks.
- **Risk-based Thinking:** Considering that the effects of uncertainties are incorporated as “risk-based thinking”, the effect of uncertainty is seen as a deviation from what was expected. These deviations can be negative (i.e. a threat) or positive (which can be an opportunity). The explicit requirement for “Preventive Action” was replaced with the application of risk-based thinking. There is no requirement for formal risk management or an ISO 31000 compliant risk management system. The organization can decide on its level of application of risk-based thinking and the actions it takes to address risk, including whether or not to retain documented information as evidence of its determination of risks.
- **Scope:** The internal and external context of the organization, the needs and expectations of interested parties and the products and services of the organization have become the starting point for the definition of the QMS scope and objectives. ISO 9001:2015 does not refer to “exclusions” in relation to the applicability of its requirements to the organization’s QMS. However, an organization can review the applicability of requirements due to the size or complexity of the organization, the management model it adopts, the range of the organization’s activities and the nature of the risks and opportunities it encounters. ISO 9001:2015 only allows exclusions where the organization can prove that such exclusions do not affect the delivery of conforming products and services to their clients. NB: the scope of the QMS may differ from the scope of certification to ISO 9001:2015.
- **Leadership:** ISO 9001:2015 strengthens the requirement for top management to ensure that the QMS meets its intended results. Top management is accountable for the effectiveness of the QMS.
- **Quality Objectives:** There is an increased focus on planning to achieve the objectives, including consideration of what will be done, by whom, by when.
- **Knowledge:** ISO 9001:2015 includes requirements for determination, maintenance and preservation of organizational knowledge.
- **Documented information:** The previous differentiation between “documents” and “records” was removed and replaced with the single term “documented information”. The new requirements are to “maintain documented information” (i.e. information necessary for the organization’s QMS) and to “retain documented information” (i.e. provide evidence of actions carried out or result achieved). A stand-alone document called a Quality Manual is no longer required. Unless the standard specifically requires that documented information to be maintained or retained, it is at the discretion of the organization to do so.
- **Externally provided processes, products, and services:** Information for external providers is now more detailed and explicit and includes inter alia the *approval of products, services, methods, processes and equipment, required competence/qualifications, interactions with other organizations, and monitoring*

# 1 INTRODUCTION

*of the external providers' performance.*  
In an engineering consulting context this applies particularly to the subcontracting of engineering services.

For further information on changes from ISO 9001:2008 to ISO 9001:2015, see the Introduction and Annex A in ISO 9001:2015.

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## 1.3 Transition from ISO 9001:2008 to ISO 9001:2015

Compared to former revisions, firms gain some more freedom in setting up and tailoring their QMS. The structure, format, style and medium of documented information remains at the sole discretion of the firm, based on the size of the organization, complexity of processes and competence of persons. Any (mostly electronic) access to hands-on tools and templates can, be as intranet, a wiki format or an app solution.

The transition to ISO 9001:2015 can be used as trigger for revitalizing the existing QMS. If the existing QMS has been aligned to the clause structure of an earlier version of ISO 9001, the transition presents an opportunity to revise documentation of the firm's management system to better reflect its organizational structure, processes and business objectives.

The extent to which the new requirements of defining the context, applying risk based thinking and knowledge management are implemented, is at the discretion of the firm. No full-blown solutions like extensive risk registers, semi-quantitative assessments, elaborate management information systems, or explicit knowledge databases are needed if the same

purpose can be achieved by an occasional SWOT (strengths, weaknesses, opportunities and threats) analysis, brain-storming, a simple skill matrix and internet links.

As project-oriented organizations, engineering firms need to consider both the overall organizational framework and the management of individual projects. For instance, risk-based thinking not only applies to developing a promising market opportunity and recruiting the right staff, but also to meeting the challenges of the specific project. In fact, talking openly about relevant interested parties, success factors and likely obstacles, and implementing proactive risk and issue management in projects may well be the main benefit of the transition to ISO 9001:2015.

Note that certifications to ISO 9001:2008 become invalid on 14 September 2018. Refer to the IAF ID 09 <http://www.iaf.nu/upFiles/IA-FID9Transition9001PublicationVersion.pdf>

A detailed correlation list of the requirements of ISO 9001:2008 and ISO 9001:2015 (in either direction) is available from <https://committee.iso.org/tc176sc2>

## 2 APPLICATION OF ISO 9001:2015 TO CONSULTING ENGINEERING SERVICES

### 2.1 Introduction

The ISO 9001:2015 standard requires that all the processes needed for QMS be planned, implemented and maintained. This includes processes for the provision of products and services. In the engineering context this refers to a significant extent to providing services to clients. It is important to emphasize that the output of a consulting engineering firm, e.g. an engineering design which may include deliverables such as drawings, models and reports, project management, construction monitoring, expert witnessing and advisory services (or any combination thereof) is not to be confused with the product which is created based on the consulting engineer's output (e.g.

the constructed piece of infrastructure). The exceptions are types of contract such as Design & Construct (D&C) or Engineering Procurement and Construction (EPC) where the consulting engineering firm takes on the role of contractor.

Note that separating design from construction is particularly applicable to the building process and not encountered in all consulting engineering services.

Each consulting engineering firm therefore needs to consider which processes it operates in providing its services.

### 2.2 Scope of the Quality Management System

ISO 9001:2015 Clause 1, "Scope" defines the scope of the standard itself. This should not be confused with the scope of application of the engineering firm's QMS nor with the scope/extent of its certification to the standard.

For many firms the QMS will apply to all services provided. However, some firms may decide not to cover all of their services, whether defined by service type or by geographical area of operation. As an example, a firm may decide (at least initially) to limit the application of the QMS to its civil engineering services, or to those services provided in its home country. In many cases, such restriction is used in order to place priority of certain services or areas of operation,

with the QMS being progressively expanded to cover other services or other geographic areas of operation over a period of time.

If a consulting engineering firm chooses to implement a QMS with a limited scope this should be clearly defined in documented information and any other publicly available documents (for example certification documents and marketing material). It is important to avoid confusing or misleading clients and other users.

For professional liability and public indemnity insurance, it is worthwhile to confirm with relevant insurer(s) that they are comfortable with the scope defined for the firm's QMS.

### 2.3 Exclusions from the ISO 9001:2015

Most consulting engineering firms may find it advisable not to exclude any requirements, even if some do not currently apply. The standard places stringent requirements on the justification for any exclusion, i.e. exclusions can only be justified if the organization's ability to achieve conformity of products and services is not compromised.

For example, a firm may consider excluding requirements as specified in clause 7.1.5 *on Monitoring and measuring resources* if no monitoring or measuring devices are

used for any purposes, including indicative measurements, such as those used in monitoring construction activities. Where devices such as measuring tapes and electrical meters are used only for indicative purposes, parts of clause 7.1.5.2 dealing with calibration and verification of devices may be excluded. However, whenever the work of contractors may be accepted or rejected by such measurements, devices must be controlled in accordance with 7.1.5 – an exclusion would not be justifiable in this case without compromising the conformity of the service rendered.

## 2 APPLICATION OF ISO 9001:2015 TO CONSULTING ENGINEERING SERVICES

Electronic tools and smart phone apps are increasingly used for measurement purposes (e.g. vibration detection). It is imperative that a process for calibration is established if such tools/apps are used for more than indicative purposes. In some cases the manufacturer's documentation may provide evidence of the reliability of calibration status (e.g. the ability of certain pieces of equipment to self-calibrate).

Some consulting engineering firms have suggested other clauses for exclusion, for example:

- Firms which carry out only design and development activities may wish to avoid duplication between the requirements of 8.2 *Requirements for products and services* and 8.3 *Design and development of products and services*. However, rather than excluding either of these clauses, the firm needs to consider applying them together, i.e. the methodologies and control of both clauses within one process.
- The same applies to the requirements for 8.3 *Design and development of products*

*and services* and 8.5 *Production and service provision*. Some firms consider that their services do not extend beyond design. However the overall service to a client needs to be considered. The requirements of both clauses can be dealt with together so that the firm's processes can be applied to both design and non-design services.

- Firms may consider that requirements for design and development validation as per clause 8.3.4 item d) and e) can be excluded, because design validation can only be completed after the product is produced or constructed. Where testing/ inspection of a constructed asset is not possible/ where the appointment of the firm does not include involvement in the construction/ construction monitoring of an asset, the firm can consider alternative validation methods including computer simulation or comparison with, and "lessons learned" from, similar designs performing an equivalent purpose and operating in an equivalent environment.

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### 2.4 Further Guidance on Application of ISO 9001:2015

ISO has published a number of guidance documents related to ISO 9001:2015. Of particular interest to the consulting engineering industry are

ISO 10005 Quality management systems — Guidelines for quality plans

This provides guidance applicable to both the consulting engineering firm itself

and to assist the firm to specify quality plan requirements for other parties to a project.

ISO 10006 Quality management systems — Guidelines for quality management in projects

This guidance is applicable to any size and type of project.

### 3 INTERPRETATION OF ISO 9001:2015 REQUIREMENTS FOR THE CONSULTING ENGINEERING INDUSTRY

The sections in this chapter are structured following the ISO 9001:2015 chapters, in the following manner:

- **Standard**, stating the heading of the ISO 9001:2015 clauses for ease of reference
- **Purpose**, a short description of the relevance to engineering firms
- **Guidance**, discussing the interpretation of that clause and its application by consulting engineering firms.

The Guidance largely uses the word client where the Standard uses the word customer. However, it should be recognised that the term customer in the standard also includes end users of the product or service. Their needs should be considered for example in determining project risks.

#### Ch. 4 – Context of the organization

##### Standard

##### 4.1 Understanding the organization and its context

##### Purpose

To understand any relevant internal and external issues that can affect either positively or negatively the intended results of the QMS and/or the firm's overall strategic direction.

##### Guidance

Understanding external and internal issues is necessary as a foundation to meaningfully tailor QMS elements including processes, policy and objectives, risks and opportunities.

##### External

- Macro-economic factors such as currency exchange rate predictions particularly for international projects or multinational engineering firms, the general economic situation, availability of project finance, national infrastructure development plans
- Social factors such as communities affected by projects, educational levels, pipeline for engineering graduates, emergence of new delivery models such as EPC (Engineering, Procurement, Construction), EPCM (Engineering, Procurement, and Construction Management), D&C (Design and Construct)

- Political factors such as political stability e.g. in project locations, public investments, especially in local infrastructure
- Technological factors such as new sector technology (e.g. digital disruption, advances in multi-dimensional building and infrastructure information modelling (BIM) and multi-dimensional design tools), professional codes of ethics
- Competition, including the firm's market share, market leader trends, market stability, market consolidation through mergers and acquisitions
- Factors which affect the work environment such as trade union regulations, legal and statutory requirements (e.g. environmental legislation and codes) and engineering standards.

##### Internal

- Overall performance of the firm, including financial results, as well as the firm's strategic objectives and direction
- Resource factors, including infrastructure (office and site facilities as well as software programmes such as those used for design and drafting), environment for the operation of the processes and organizational knowledge
- Human aspects such as competence of persons, organizational culture, language of users of documented information, cultural sensitivity, diversity, stress management and mental health, support for personnel on remote sites
- Operational factors such as processes, project track record and experience, performance of the QMS, customer evaluations, change management
- Factors in the governance of the firm, such as processes for decision making, the firm's structure and business continuity planning.

##### Standard

##### 4.2 Understanding the needs and expectations of interested parties

### 3 INTERPRETATION OF ISO 9001:2015 REQUIREMENTS FOR THE CONSULTING ENGINEERING INDUSTRY

#### Purpose

To consider the needs and expectations not only of clients but also other interested parties in strategic planning, both at the enterprise level and in relation to specific services, to protect the QMS from negative impacts while enhancing potential positive impacts.

#### Guidance

An engineering consultant firm can be impacted by changing expectations of clients overall, for example for communication of technical issues, responsiveness to community concerns and use of emerging technology. Projects can be impacted by matters such as environmental and social permits, authorizations, expectations of local communities in vicinity to project sites and many other matters. In order to be effective it is important to focus on relevant interested parties and to prioritise the needs and expectations to be considered. Relevant interested parties, and their needs and expectations, will change over time. Examples of such interested parties include:

- end users (e.g. tenants/prospective tenants of buildings designed by the firm)
- owners, shareholders
- providers of project finance including financial institutions, aid agencies etc
- external providers (e.g. sub-consultants, joint venture and alliance partners)
- other external parties involved in a project
- employees and others working within the firm
- legal and regulatory authorities (local, regional, state/provincial, national or international)
- trade and professional associations (e.g. professional registration bodies)
- local community groups
- non-governmental organizations
- local neighbouring organizations/activities in the locality
- competitors.

Interested party requirements may include, but are not limited to:

- contracts which have been entered into with clients or external providers including memoranda of understanding
- conformity to industry codes and standards (e.g. engineering specifications)
- agreements with community groups or non-governmental organizations (e.g. outcomes of social impact assessments);
- legislation (consider both the legislation in the firm's location as well as the project location)
- permits, licences or other forms of authorization
- voluntary principles or codes of practice
- voluntary labelling or environmental commitments (e.g. national Green Buildings and/or Green Roads Councils).

You may develop relevance criteria by, for example:

- their possible influence or impact on the firm's overall performance or a specific project
- their influence on risks and opportunities
- the level to which they can be affected by decisions or activities of the firm.

#### Standard

##### 4.3 Determining the scope of the quality management system

#### Purpose

To have a clear understanding – both within the firm and in the way the firm communicates about their QMS externally – of what is/ is not addressed in the QMS. This applies to both products/services provided and geographic areas covered by the QMS.

#### Guidance

The scope needs to take into account your firm's products and services, considering such issues as:

- different office locations, engineering disciplines and projects
- which processes and/or activities are managed or performed by different parts of the business

### 3 INTERPRETATION OF ISO 9001:2015 REQUIREMENTS FOR THE CONSULTING ENGINEERING INDUSTRY

- which processes are externally provided (outsourced), e.g. provided by sub-consultants, or in collaboration with joint venture or alliance partners
- organizational capabilities to provide specific services
- financial drivers, e.g. scope of professional liability insurance cover.

The scope and justification of any possible exclusions need to be maintained as documented information.

#### Standard

#### 4.4 Quality Management System and its processes

#### Purpose

To ensure that the QMS is created in a value-adding manner, enhancing synergies between processes, reducing disruptions at process interfaces, with the overall aim of creating products/services which conform to requirements.

#### Guidance

This clause refers to all the processes that your firm needs to achieve its planned results, not only the processes to deliver engineering services. Apart from the requirements for documented information which the firm must compile, there is no rule on which processes the firm has to provide as documented information or the level of detail required. Simple processes might require only simple explanations. Complex processes will require sufficient explanations to enable people to understand the activities and tasks, and the inter-relationships, to the extent necessary to effectively implement their roles.

Firstly consider any processes related to your engineering services and projects. Consider that many high level processes such as strategic planning, project planning, project execution and project close out, might be broken into smaller sub-processes. For example, project planning might have sub-processes for planning design and drafting, planning engagement with interested parties, planning issue of drawings etc. The documented information relating to processes only needs to go to the level of detail which is meaningful and value-adding to your firm.

Secondly consider non-project related/administrative processes, which are nevertheless needed for successful provision of the engineering consultancy's services. These may include:

- information management (e.g. sourcing of relevant design specifications applicable to project location)
- documented information management including retention and archiving of deliverables in line with applicable requirements, electronic information management (backups, crisis preparedness)
- human resources (e.g. recruitment, competency, performance management, training, staff mobility, succession planning)
- facilities management
- process monitoring.

When developing and optimising the overall system of interrelated processes, consider risks and opportunities associated with each process. For example you might wish to consider possible disruptions caused by failure of IT infrastructure on a project site or the insurance requirements related to maintaining correct professional registration, etc. Your processes need to protect you from such risks materialising while enhancing your ability to maximise benefits from opportunities and foster innovation.

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## Ch. 5 – Leadership

#### Standard

#### 5.1 Leadership and commitment

#### Purpose

To ensure that the quality policy and quality objectives are entrenched into the organization through visible and proactive leadership by top management and that the firm and its top management are committed to the effectiveness of the QMS.

#### Guidance

Top management is defined in ISO 9000:2015 as the “person or group of people who direct and control the organization at the highest level”, e.g. the owner(s) of a small firm or an executive committee in a larger organization.

### 3 INTERPRETATION OF ISO 9001:2015 REQUIREMENTS FOR THE CONSULTING ENGINEERING INDUSTRY

The intent of this requirement is for top management to provide leadership of and commitment to the QMS, establish the roles, authorities and responsibilities necessary for its effectiveness and ensure the achievement of planned results. Top management is accountable for the successful implementation and maintenance of the QMS, even where people at lower organizational levels are responsible for performing specific activities and tasks.

Top management can demonstrate fulfilment of their authorities and responsibilities by ensuring the achievement of the planned results, and:

- a) ensuring that the QMS continues to be suitable and effective, through continual performance monitoring and measurement;
- b) taking account of the internal and external context and strategic direction, when maintaining the quality policy and objectives, to ensure that they are aligned with overall business processes;
- c) ensuring that there is understanding of the process approach and that QMS processes interface with the processes of other functions (e.g. finance, human resources, facilities management, marketing, etc.) within your firm, so that inputs and outputs between processes are coordinated effectively;
- d) monitoring the current and projected workload and schedules so that adequate QMS resources (human, tools, equipment etc.) are provided, when and where needed;
- e) communicating, via appropriate communication channels the value of the QMS and adherence to its requirements including benefits such as client retention, increased market share, avoidance of cost of rework;
- f) ensuring that information and recommendations from internal, second and third-party audits and management reviews are communicated to responsible parties within the firm;
- g) monitoring the outputs of the QMS, and ensuring that the relevant responsibility, authority and resources are assigned for corrective actions when intended results are not achieved;
- h) providing support and guidance in the interpretation and understanding of statutory

and regulatory requirements.

A key success factor for implementing a value-adding and well-entrenched QMS is to have top management actively engaged, understanding how quality relates to critical business issues.

#### Standard

#### 5.2 Policy

#### Purpose

To ensure that top management aligns the quality policy with the firm's strategic direction.

#### Guidance

A quality policy is a cornerstone of any QMS. It establishes:

- a commitment to quality
- a commitment to continual improvement of the QMS
- the context for quality objectives and how they relate to client requirements.

The quality policy needs to describe the overall vision of what quality means to the consulting engineering firm and its clients. The quality policy would normally cover:

- commitment to determining and meeting client needs and expectations
- management's expectations of employees
- the general approach to achieving intended results.

The quality policy needs to be authorised by top management.

The quality policy will probably form part of at least some proposals to clients and is generally available as a public document. Remember that your clients are entitled to assume that you do what you say in the quality policy.

In maintaining the quality policy, the firm needs to consider:

- a) how achievement of the objectives will be demonstrated;
- b) how the commitment to satisfy requirements will be demonstrated;
- c) what performance measurements and analysis will demonstrate your firm's commitment to continual improvement.

## 3 INTERPRETATION OF ISO 9001:2015 REQUIREMENTS FOR THE CONSULTING ENGINEERING INDUSTRY

### Standard

#### 5.3 Organizational roles, responsibilities and authorities

### Purpose

To ensure that everyone knows what they are expected to do (responsibilities) and what they are allowed to do (authorities).

### Guidance

There are different ways in which roles, responsibilities and authorities can be defined, and it is up to the firm to decide what works for them. Various types of documented information including procedures, work instructions, position descriptions, organization charts and/or responsibility-authority matrices are useful tools to define where one person's responsibilities and authorities end and those of another person start. It is important to define the responsibility for the effectiveness each process, particularly where a process crosses various functional/departmental boundaries (sometimes known as "process owner"). Process ownership mapping is often in contradiction with the organization chart – make sure it is consistent.

You can use specific fields in your documented information where the responsibilities and authorities are defined (e.g. special columns in procedures). In an electronic environment, specific log-in credentials assigned to specific roles/positions might give you access to functionalities associated with the role (e.g. adding electronic signatures, approving a workflow to proceed to the next stage etc.).

Things to consider:

legal, statutory and regulatory requirements, professional code of ethics. In an engineering environment consider for example professional registrations that are needed for authorising drawings, approving environmental impact assessment or acting as a quantity surveyor. The professional registration or licensing requirements pertaining to the project location have to be adhered to.

- available resources for the effective operation of the processes
- ensuring consistency between assigned responsibilities and any related documented information

- delegation of authority - including during absence - needs to be defined and communicated to relevant parties.

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## Ch. 6 – Planning

### Standard

#### 6.1 Actions to address risks and opportunities

### Purpose

To consider risks and opportunities when planning the QMS, taking account of the organizational context and the needs and expectations of interested parties.

### Guidance

There are risks and opportunities in all systems, processes and functions. The aim of risk-based thinking is to proactively address the risks and/or to seek ways in which to leverage opportunities. The aim of risk-based thinking in ISO 9001:2015 is not that engineering firms have to implement formal risk management, but that consideration of both risk and opportunities flows into the planning and maintenance of the QMS. Formal risk management processes may however be required on a project by project basis in line with client requirements.

If your firm deals with specific technical risks on a regular basis, the firm needs to consider which processes might be employed to address the risks systematically, e.g. providing work instructions, guidance material, training and awareness for engineering staff on how to handle the specific technical risks.

There are various ways in which risks can be addressed: you can avoid the risk entirely (e.g. not pursue a project at all), change the likelihood of the risk occurring or the severity of the consequence should the risk materialise. You can also share the risks, or even retain the risk by informed decision.

Risks and opportunities often go hand in hand. New technologies in engineering, the emergence of new markets, new clients etc. might, for example, expose a firm "to being left behind", but on the other hand the firm might position itself favourably. When determining mitigation actions, the firm should thus not limit their considerations on how to avoid negative impacts, but also whether there are ways to enhance positive impacts.

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In order to determine risks and opportunities, the firm can use the following inputs and techniques:

Minutes of meetings, brain storming, SWOT analysis, reports on clients feedback, competitor analysis, market research, analysis and evaluation activities, and information from corrective actions.

#### Standard

##### 6.2 Quality objectives and planning to achieve them

#### Purpose

To define the firm's overall quality objectives, as well as tracking progress towards achievement of them.

#### Guidance

Objectives in the sense of ISO 9001:2015 are not mere, vague statements of intention. They give the firm a means to track whether they are making progress towards achieving promises and undertakings made in the quality policy and to ensure products and services are conformant to requirements. Some of the ground rules of quality objectives are that they:

- have been defined
- reflect the quality policy
- must be substantially coherent
- are aligned and compatible with the organization's context, strategic direction, business goals and client expectations
- are available as documented information
- must be measurable either quantitatively or qualitatively.

Where appropriate, objectives may need to be set at different levels and functions in the firm so that each part of the firm can play a role in achieving an overall goal. Objectives also need to be communicated to align everyone's activities towards the common goal. Progress needs to be monitored. If objectives are no longer meaningful in their current form, they need to be updated as appropriate.

ISO 9001:2015 gives self-explanatory requirements on how the firm needs to pursue its objectives. In essence, an engineering firm should have a documented plan on how its objectives will

be actively implemented and achieved.

#### Standard

##### 6.3 Planning of changes

#### Purpose

To ensure that changes are carried out in a planned manner.

#### Guidance

A QMS needs to be responsive to changes in the business context and the needs and expectations of interested parties. Changes to the QMS need to be planned and implemented in a systematic and controlled manner, while maintaining the operational activities. When making changes, consider whether a change in one part of the QMS might result in inconsistencies or errors in related processes.

Practical considerations include the resources needed for implementation and adoption of the change within the firm.

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### Ch. 7 – Support

#### Standard

##### 7.1 Resources

###### 7.1.1 General

#### Purpose

To ensure that sufficient resources are available for the establishment, implementation, maintenance and continual improvement of the QMS.

#### Guidance

The firm needs to evaluate their resource needs. Resource needs should be reviewed on a regular basis and as required for specific projects.

The resources to be considered include people, infrastructure, environment for the operation of processes, monitoring and measurement resources and organizational knowledge.

#### Standard

###### 7.1.2 People

A consulting engineering firm requires appropriate human resources for the operation and control of its processes including people

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within the firm and those externally sourced to meet business needs.

#### **Standard**

##### 7.1.3 Infrastructure

Infrastructure includes buildings (also temporary infrastructure, such as containers and other on-site equipment incl. maintenance), equipment such as hardware and software, transportation resources, information and communication technology. A consulting engineering firm needs to consider infrastructure such as design software packages, document information management tools and remote connectivity for off-site work.

#### **Standard**

7.1.4 Environment for the operation of processes

In the engineering consulting industry, both human and physical factors can play a role in productivity, engagement and ultimately conformity of products and services. Special consideration needs to be given to work being conducted in remote locations or workplaces away from the office.

#### **Standard**

##### 7.1.5 Monitoring and Measuring Resources

In the consulting engineering industry, you will come across many monitoring and measurement tools, such as theodolites, nuclear density gauges, measuring tapes, as well as engineering materials and laboratory equipment.

Many consulting engineering firms use monitoring and measuring resources only for indicative purposes. Such resources need to be fit for purpose.

Monitoring resources also include tools and techniques which deliver non-quantitative results. Such tools and techniques also need to be fit for purpose, for example checked for consistency and processing of data.

However, where firms use measuring and monitoring equipment including field and laboratory equipment to ensure that measurement and test results are traceable to national or international standards, such

equipment needs to be verified and calibrated in line with legislation, user manuals from the manufacturer of the equipment, etc. The equipment needs to be verified as being serviceable for use (in good working order), and calibrated periodically to confirm its continuing capability to meet the measurement accuracy for its application. "Periodically" can mean on a time basis (for example, monthly or annually) or on a usage basis (for example, before each use for infrequently used equipment, after transportation, etc.). Verification can usually be done by the user according to a written instruction developed by the consulting engineering firm, or supplied by the manufacturer of the equipment. Calibration is often done by competent, and where appropriate accredited, external agents. Processes for the control of monitoring and measuring equipment need to be established. To ensure that the equipment operates effectively and gives reliable results, documented information should address the following:

- Methods to ensure that the equipment is suitably looked after (for example, correctly handled, stored and maintained), regularly checked, adjusted, verified and calibrated, as necessary
- Documented information needs to be retained to show the control of the equipment and, if applicable, that calibration is traceable to national or international standards
- Means of identifying the calibration status and suitability of the equipment for use. This may be achieved by labelling the equipment or by provision to the user of calibration records
- Action to be taken if the equipment is found not to conform to requirements, including review of prior measurements made with the equipment, when it was possibly faulty.

For further information refer to ISO 10012.

#### **Standard**

##### 7.1.6 Organizational Knowledge

Organizational knowledge is the specific knowledge needed in the provision of products and services and for the firm to operate effectively. It can be generated from internal sources

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(intellectual property, collective and individual experience, lessons learnt from failures and successful projects) as well as external sources (e.g. standards, reference libraries, academia, conferences, knowledge gained from clients and sub-consultants/external providers, networking and digital media).

What the standard requires is that the engineering firm firstly determines which knowledge is needed for the engineering consultancy services which are offered. Secondly, this knowledge needs to be made available, preserved and/or protected to the extent necessary. Also consider how to acquire or access any necessary additional knowledge. There might be value in maintaining knowledge as documented information.

Organizational knowledge management is not limited to documented information. Specialist knowledge is often held by individuals and in some cases may influence the strategic decisions of the firm. Where persons with specialist knowledge leave the firm, the impact on organizational knowledge needs to be considered.

#### **Standard**

##### **7.2 Competence**

#### **Purpose**

To ensure that people carrying out work that affects the performance and effectiveness of the firm are competent.

#### **Guidance**

The competence of persons in a consulting engineering firm has a direct influence on the quality of the services provided. All activities that affect quality need to be performed by people who have the necessary qualifications, training, experience, knowledge and skills, and who can be trusted to make sound professional judgements.

Competence can be gained through appropriate education, training, induction, mentoring and experience. An organization typically needs to determine which competencies are required, then identify and address any competence gaps. Competence needs to be periodically reviewed.

Note the difference between knowledge and competence. Competence is the ability to act responsibly, by virtue of experience and authority

to make decisions. Knowledge alone will not lead to competence.

When addressing competency, the firm needs to include people who are not directly involved in providing engineering consultancy services, e.g. administrative, marketing and other support personnel. Particularly in a smaller firm almost everyone can affect the conformity to product and service requirements in some way. The firm should find mechanisms to keep competence up-to-date, e.g. by offering re-fresher training. Furthermore, the firm needs to evaluate the effectiveness of any actions taken, using techniques such as direct observation of a person's performance as well as assessing the results of tasks and projects.

The firm needs to retain appropriate documented information to provide evidence of employee competence, taking account of applicable regulatory requirements regarding qualifications, mandatory training, licenses or similar.

#### **Standard**

##### **7.3 Awareness**

#### **Purpose**

To ensure that people doing work under the organization's control are aware of the QMS and the firm's strategic direction.

#### **Guidance**

Awareness of the QMS includes the quality policy, objectives, how they as individuals and groups contribute to the effectiveness of the QMS, and the implications of not conforming with QMS requirements. This applies not only to permanent staff, but to anyone possibly affecting product or service quality - temporary staff, sub-consultants, contractors, volunteers, etc.

#### **Standard**

##### **7.4 Communication**

#### **Purpose**

To ensure that internal and external communication is relevant, effective and aligned to the firm's strategic direction.

#### **Guidance**

It is crucial to the success of a consulting engineering firm that people are fully involved in achieving the firm's objectives. Therefore

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management needs to actively encourage feedback and communication from all people within the firm. Effective processes should be established for communication at all levels, and in both directions.

The firm needs to ensure that the objectives and measures of effectiveness of the management system are communicated and understood throughout the firm. A variety of communication channels are available, e.g. traditional (department meetings, debriefings, recognitions of achievement, round table meetings, lunch and learn sessions, newsletters, notice boards, posters, flyers, advertising), current technology (emails, texts, intranet, project extranets, websites, blogs, social media) and emerging methods (apps, improved teleconferencing and data sharing). The firm needs to select communication channels that match its culture, structure and processes.

Communication within projects and discipline groups often needs specific attention to ensure that the firm is open to innovation, learns from its experience and captures the knowledge that it develops in the course of its work.

For external communication, the firm may need to plan who is authorised to communicate on behalf of the firm (e.g. communication with media, crisis communication, clients and relevant interested parties).

#### Standard

##### 7.5 Documented Information

#### Purpose

To ensure that people have the information they need to do their job when they need it, where they need it and that quality management processes provide appropriate evidence of conformity to requirements.

#### Guidance

A firm can control its processes in different ways, using different media, language, software, images and graphs. Some consulting engineering firms use procedures, work instructions and forms – other firms use electronic media with workflows including different stage gates and controlled access rights. A firm might use a mix of these depending on the nature and scale of different projects being delivered.

ISO 9001 uses the single term “documented information” but differentiates as follows:

- a) “maintain documented information” (i.e. information necessary for the firm to operate and establish a QMS, e.g. procedures, templates or workflows), and
- b) “retain documented information” (i.e. provide evidence of actions carried out or results achieved, e.g. completed forms, authorised project plans, issued drawings, amendment control).

The firm needs to determine which documented information needs to be protected for reasons of confidentiality, security of intellectual property or the integrity of the QMS. The firm needs to consider continued legibility, loss of integrity and disposition of retained documented information.

#### Documented information to be maintained

The purpose of maintaining documented information is to ensure that correct information is available to those who need it, and that incorrect, unauthorised or superseded information is not used.

Control means having a systematic, pre-planned approach to preparation, unique identification, review, approval, distribution, availability, storage and change of documented information. This includes documents, computer software, models, representative samples, workflows and data generated, used, stored, and transmitted by electronic means.

Maintained documented information can include:

- documents controlling the operation of the QMS e.g. description of the organizational processes, Quality Policy, objectives, workflows, procedures, work instructions, templates
- project planning documents including quality plans
- externally generated documents relevant to conformity of products or services, e.g. industry standards, specifications, statutory and regulatory requirements, user manuals, computer programs/ mobile apps, preferred external provider lists.

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### Documented information to be retained

Retained documented information (sometimes referred to as “records”) demonstrates conformance with the standards and with specified requirements. ISO 9001 specifies some mandatory documented information to be retained. The firm may decide to retain further documented information for operational, contractual or legal reasons.

The type of documented information a consulting engineering firm may need to retain includes:

- project inputs, design and development inputs
- intermediate outputs such as versions for checking, reviewing, verification, client review as appropriate
- final deliverables (e.g. final reports, approved drawings, specifications and final calculations)
- documented information as evidence of verification and validation activities (e.g. contract reviews, meeting minutes, evaluation of suppliers, inspection/check of purchased items or services, design/project reviews, checks of documents, site diaries, review of changes, calibration certificate)
- documented information demonstrating operation of the QMS (e.g. audit results, management review minutes, nonconformity reports, evidence of corrective action, and skills and competence status of the employees).

Documented information retained as evidence of conformity needs to be protected from inadvertent or deliberate alteration, physical damage, loss and unauthorised access.

For further information refer to:

- ISO/IEC 27001 Information Security Management
- Guidance on the Requirements for Documented Information of ISO 9001:2015 at <https://committee.iso.org/tc176sc2>.

### Ch. 8 – Operation

#### Standard

##### 8.1 Operational planning and control

### Purpose

To describe how the consulting engineering firm will get the work done.

### Guidance

“Operation” deals with the processes required to produce products and services of the consulting engineering firm. The deliverables can be reports, specifications, drawings, surveys, bills of quantities, models and software packages. Many firms provide a range of professional services other than design, such as studies, inspection, advisory and project management services. The processes by which the firm carries out the full range of its services need to be planned, developed and implemented.

Many of the processes needed are generic and apply to the provision of all products and services. Requirements for “Design and development” in Clause 8.3, as it relates to the consulting services, should be interpreted as design and development services to be provided to the client. Consulting engineering firms sometimes regard design and development as the only service provided to clients. However such an approach can overlook some aspects of the service as the client sees it, in particular, post-delivery and release activities referred to in Clauses 8.5 and 8.6

Clauses 8.1 to 8.7 should therefore be taken into account in planning the processes required to provide the firm’s services. For design and development services, the firm can consider the requirements of Clauses 8.3 and 8.5 together, i.e., apply the methodologies and controls described in Clause 8.3 within the requirements of 8.5. However, it is important to have a clear understanding of the whole offering to the client, including:

- communication matters such as progress reporting and the presentation of deliverables
- direct advisory services
- project completion actions, such as the care of closed project files.

The key generic processes for service provision will generally need to be documented. Depending on the size and complexity of the firm, these may be simple flow charts or more detailed documents. Unique project requirements can be

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set out in a project quality plan, which can also reference generic processes.

#### Standard

#### 8.2 Requirements for product and services

##### Purpose

To make sure that:

- proper communication with the client is established and maintained
- the consulting engineering firm and the client share a common understanding of what is to be done
- the consulting engineering firm understands and can meet the client's requirements
- all other relevant requirements are identified
- changes to requirements are reviewed and communicated to everyone affected.

##### Guidance

Requirements for products and services not only relate to the product or service itself, but also to the way in which the firm communicates with clients. Communication with clients has to include specific, mandatory matters, e.g. providing information relating to the products and services, handling enquiries, contracts or orders, changes (including scope changes), obtaining feedback from clients, relating to products and services including complaints, handling of clients property including IP and any contingency actions.

The consulting engineering firm needs to determine the client's requirements, both those explicitly expressed and implied. It is often not possible to rely on requirements as defined by the client, for example in tender documents, since these are unlikely to cover all statutory and regulatory requirements, applicable standards, or requirements, which are the responsibility of the consulting engineering firm. Further, the client may not be able to identify and formulate the needs into requirements. It is critical that the consulting engineering firm takes adequate steps to clearly identify all requirements.

Establishing client requirements, developing a brief, and interacting with the client and other parties, to achieve and maintain documented agreement as the project evolves, can be a major

task for a consulting engineering firm.

The review of the requirements needs to be done, as far as is practically possible, before the consulting engineering firm commits itself to accepting the work. This may not always be possible. It may be necessary that the review process be extended to contract negotiations and post-award communications with the client. Special attention needs to be paid to the information that the client agrees to provide, and the client's involvement during the conduct of the project.

The process for preparation, review and approval of a proposal or contract submission, and the records to be maintained, generally needs to be documented in a procedure or other process description.

#### Standard

#### 8.3 Design and development of products and services

##### Purpose

To translate the client's requirements into project specific design or development documents. This includes:

- Planning: to describe how the firm is going to plan the processes for the conduct of design and development activities of the project
- Inputs: to identify what input information is essential for the project
- Controls including review, verification, validation and retention of documented information
- Output: to define the project deliverables
- Design controls: review, verification, validation
- Changes: to control any changes to the project.

##### Guidance

The requirements of ISO 9001:2015 for design and development planning, design and development inputs and design and development outputs are self-explanatory

Requirements for design and development controls include review, verification, validation and other necessary activities. The firm needs

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to determine the type and extent of these control activities appropriate to each project, and the documented information to be retained.

#### ***Design and development reviews***

Review is the formal evaluation of the project work, to confirm that it meets the client's needs and other input requirements, to identify if there are any problems, and to develop solutions for these problems.

Reviews can take place throughout the project. Their frequency is a function of the size and complexity of the project, and/or specified in the contract. The project team needs to decide what the appropriate stages for reviews are, the scope and objectives of the reviews, and the persons who should be involved in them. A complex project may require many reviews, and may need to include additional experts from within the firm, as well as external experts and client representatives. A simple project may require only one review. For small projects, such as those not involving subconsultants or other design groups, one person may conduct the review. Details of the planned design reviews should be incorporated into the project quality plan.

The review needs to identify and anticipate risks and opportunities, and should initiate actions to ensure that the deliverables meet client requirements. A review needs to consider aspects such as client requirements, sequence of design activities, compliance with the design brief, identification and control of interfaces, construction processes, safety and methods of verification.

Documented information on the design and development reviews, and any necessary actions needs to be retained. This can include notation on a document, minutes of a meeting, etc.

#### ***Design and development verification***

Verification is an activity designed to ensure that the output to date meets the specified requirements.

Deliverables and intermediate outputs (e.g. calculations, drawings, specifications, bill of quantities, reports, data sheets, etc.) need to be verified in accordance with design and development planning. The verification needs to be performed by authorised personnel having

the competence and ability to operate effectively, without being constrained in any way. In the case of multidisciplinary projects, the verification may involve persons of various disciplines. The verification may be more or less sophisticated, according to the project needs. The use of models, prototypes or computer simulations may be appropriate. Evidence of the verification, and any necessary actions, need to be retained as documented information.

The verification should, to the extent necessary, cover interface aspects, constructability of the project, safety, reliability, environmental aspects, maintainability, operability, availability and feasibility.

#### ***Design and development validation***

Validation of the project is the process of ensuring that the physical product (for example a bridge or a plant) will or does meet the client's needs or the intended use.

Wherever practicable, validation should be carried out before delivery or implementation of the product. For the majority of assignments undertaken by a consulting engineering firm, such as a design assignment or a feasibility study, validation of the output can usually only be completed, when the physical object of the design or study has been realized.

Where proven design solutions are applied, there may be no need for further design validation. However it should be noted that the use of proven designs may not necessarily guarantee that all possible situations for the use of the product have been considered. Validation of designs against various possible future uses of the product may be included in design reviews.

Where unproven designs are developed, arrangements for validation need to be established, whether during the design period, the product realization phase or later.

Responsibility for validation may rest with the consulting engineering firm or with others, depending on the scope of the contract. Where unproven design solutions are to be developed, it may be necessary for the consulting engineering firm to reach agreement with the client, during the contract negotiation phase, about the scope of design validation requirements within a contract.

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When validation is within the scope of the consulting engineering firm's work on a particular project, the validation activities to be performed should be identified in the project quality plan. Adequate documented information of the validation process, including records of any necessary actions, should be retained. Evidence of such validations may provide a source of proven designs for future use.

#### **Control of design and development changes**

Where design and development changes are made, documented information of why the changes were made, the change itself, any reviews performed and who approved the changes needs to be retained.

The firm needs to establish methodology for the control of design and development changes, whether occurring due to the client's request, internal and external reviews, verification activities or site conditions. This methodology should include how changes are initiated, recorded, reviewed, approved and implemented, considering potential adverse impacts on project delivery, schedule and price. The persons authorised to approve the changes needs to be identified.

The methodology needs to provide for the timely availability of approved changes to relevant parties.

The complexity of change management will depend on the scale and complexity of the particular project. During design and development planning, decisions should be made about whether or not a comprehensive change register will be required, and how data should be recorded to enable sufficient monitoring and control.

#### **Standard**

##### **8.4 Control of externally provided processes, products and services**

###### 8.4.1 General

#### **Purpose**

To ensure that any externally provided processes, products or services contributing to the quality objectives conform to the specified requirements at both organizational and project levels.

#### **Guidance**

External provision can be from outside the consulting engineering firm or from within the firm but outside the control of the project organization. It includes the procurement of outsourced processes as well as products and services.

It is important to apply a risk-based approach in the process to control externally provided processes, products and services, applying appropriate controls based on the potential impacts on the firm's performance or a project's outcome.

#### **Standard**

##### 8.4.2 Type and extent of control

The consulting engineering firm should have controls for obtaining those processes, products and services, which may affect the quality of the firm's deliverables. The most important application of this clause in a consulting engineering firm is the selection, use, control and review of subcontracted services and partnering arrangements for projects.

The firm needs to define criteria for the evaluation, selection, monitoring and re-evaluation of external providers, which could include among others the following:

- References and market perception
- Technical expertise
- Timeliness of response and delivery
- Past experience
- Evidence of quality documentation.

Documented information on external provider evaluation should be retained.

The firm needs to define appropriate verification and other activities to ensure that the outsourced processes, products and services are capable of contributing to the quality objectives, and are in accordance with the requirements. Appropriate verification and other activities may need to be outsourced themselves, e.g. in cases where high technical risks are involved or the firm does not have the required competency to conduct these activities meaningfully. The verification can be performed for example by:

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- checking at the provider's place of business before delivery (arrangements to permit this to happen, and all associated details, need to be incorporated into the purchase order)
- checking at receipt of the processes, products or services
- checking before being incorporated into the deliverables to be provided to a client
- joint review with the provider.

Documented information on such verification and other activities should be retained.

#### Standard

##### 8.4.3 Information for external providers

For external provision of processes, products and services that may affect service quality, the firm needs to communicate to the external providers requirements for methods and controls to be applied (e.g. verification, inspection, validation and other activities), competence including qualification of persons, approval and release of products and services.

The firm needs to determine how the external provider needs to communicate with the firm and where appropriate information for external providers can be documented e.g. in the contract with the provider or in project quality plans.

#### Standard

##### 8.5 Production and service provision

8.5.1 Control of production and service provision

#### Purpose

To ensure that the provision of products and services is carried out under controlled conditions to meet specified requirements.

#### Guidance

Consulting engineering firms can find it useful to apply these requirements to the management of the overall service to the client, so that project set-up, administration, coordination and reporting activities can be integrated with design and development.

The requirements of ISO9001:2015 for control of production and service provision are mostly self-explanatory.

Regarding validation, the firm needs to consider how to manage process outcomes which cannot be tested (and held back, if unsatisfactory) between production and delivery. This is typical for services in general, but also applies to all construction items where final inspection cannot be completed before handover. The firm may consider validation outputs from similar projects as inputs to the validation process.

The retention of appropriate documented information is necessary to provide evidence that the planned arrangements have been fulfilled.

#### Standard

##### 8.5.2 Identification and traceability

Identification and traceability may be limited to individual items where requested or legally required (e.g. material certificates, welding records, etc.) or considered in the broader context of construction records and as-built documents, including photographic evidence, engineering testing results of features not accessible later, etc. Part of identification is also the comparison of assumptions in design and cost estimation with actual site conditions, particularly the accordance with the geotechnical report, but also with respect to the predicted location of utility lines. Methods for identification of products may include bar codes or QR codes.

#### Standard

8.5.3 Property belonging to customers or external providers

These requirements need to be applied in particular to intellectual property, information and personal data provided by the client or project participants. This applies to commercial and organizational information related to the client, as well as information, software or other items provided as inputs for the production and service provision. The firm needs to pay particular attention to any intellectual property or information subject to confidentiality requirements including secure disposition of documented information.

##### 8.5.4 Preservation

Preservation of product is often interpreted in a narrow sense of issuing of reports and construction

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drawings. The firm needs to bear in mind that the requirements relate to all types of deliverables and may include considerations such as use of courier services, transportation of models or samples, secure electronic transmission and safe transportation of project participants.

#### Standard

##### 8.5.5 Post-delivery activities

Post-delivery activities could be handover services (such as training of facility operators), obligations during warranty or defects liability period, or support for optimizing asset performance.

#### Standard

##### 8.5.6 Control of changes

The requirements of ISO9001:2015 for control of changes are self-explanatory.

#### Standard

##### 8.6 Release of products and services

#### Purpose

To ensure that products and services are in accordance with the requirements before delivery to the client

#### Guidance

The firm needs to consider that deliverables, which can include products such as software and documented information as well as design and development outputs, are provided as agreed, with the appropriate approvals and through the agreed communication pathways. Approval has to comply with requirements, including professional registration requirements, of the project location.

Where the engineering firm also bears the responsibility of site supervision, all inspection services may be dealt with under this clause, from verification of material conformity to factory assembly tests, site inspections, commissioning and correction of building defects.

#### Standard

##### 8.7 Control of nonconforming outputs

#### Purpose

To ensure that outputs which do not conform to requirements are dealt with systematically and the impact of the nonconformity is minimised.

#### Guidance

This clause covers process outputs, including intermediate and final products and services, not in accordance with client and other requirements. The requirements address both contractual nonconformities, including violations of agreed standards or deadlines, and shortcomings, defects or flaws in the design or other output. It relates to nonconformities detected both prior to and after release of the deliverables. These provisions also apply to output from outsourced processes.

For design work, the primary application is to ensure that non-conforming outputs are clearly identified and marked to prevent use in a subsequent process, e.g. use in a different design package or use for construction. Where practical the nonconforming output needs to be corrected and appropriately verified. Where nonconformities are detected after use has commenced, appropriate action needs to be taken.

The design and development process provides opportunities for detecting design errors or omissions during design review and verification activities. Errors or omissions identified during the iterative design and development process are usually only considered as nonconformities, if they have been caused by deficiencies in the QMS, e.g. evidence of lack of competence or inadequate control of outsourced processes.

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### Ch. 9 – Performance evaluation

#### Standard

##### 9.1 Monitoring, measurement analysis and evaluation

###### 9.1.1 General

#### Purpose

To establish the effectiveness of the QMS, using:

- planned monitoring and measurement of processes and their outputs
- data analysis and evaluation to determine effectiveness and opportunities for improvement
- information on how satisfied clients are with the products and services provided

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- information from monitoring and measurement activities and using the results to evaluate the firm's performance.

#### Guidance

Clause 9.1.1 sets out the general requirements to the consulting engineering firm to identify, plan and implement monitoring, measurement, analysis and improvement processes. It requires the firm to evaluate the performance of its QMS and retain documented information on the results. The tools and techniques used are at the discretion of the firm and dependent on factors such as size of the firm, nature of the information system, etc. Data collected needs to be meaningful and add value to the firm.

Monitoring and evaluation can be conducted at different functions and levels in the firm.

On the level of individual projects, monitoring and evaluation activities can be included in the project quality plan. Measurement can include alignment to schedules, completeness of data retention and specified project performance indicators.

On an organizational level, this can include an evaluation of overall compliance against agreed QMS related performance indicators to provide early warning signs for functions and processes needing improvement. Process management software can assist in the collection of organization-wide data.

#### Standard

##### 9.1.2 Customer satisfaction

#### Guidance

The satisfaction of the clients is an indicator of both the performance of the QMS and business effectiveness. The consulting engineering firm needs to monitor client perception of the effectiveness of fulfilling the requirements.

In the consulting engineering industry it is common to have very close relationships with the client. However, perceptions of client satisfaction alone can be misleading. It is also not acceptable to limit assessment of client satisfaction to just evaluating client complaints.

Direct measurement (for example by interviews, questionnaires or meetings) and indirect measurement (for example by monitoring

client feedback or loss of established clients) can be used to measure and monitor client satisfaction. Each method has advantages and disadvantages, and each consulting engineering firm must decide which methods are to be used generally in the firm and towards each individual client.

#### Standard

##### 9.1.3 Analysis and evaluation

#### Guidance

The availability of data for analysis and evaluation may depend on the size of the firm, the nature of the projects it undertakes and the degree to which data is captured by organizational and project software. One of the results of evaluation may be the identification of additional areas where monitoring and measurement would be of value.

Analysis and evaluation of management processes is likely to not only provide information about the firm's performance but also enable data-based decisions on opportunities such as on improving recruitment and professional development of personnel, enhancing organizational knowledge and increasing management efficiency,

#### Standard

##### 9.2 Internal audit

#### Purpose

To enable the firm to determine the effectiveness of the QMS

#### Guidance

Audits should determine whether the QMS is effective and suitable for achieving the quality policy and the stated quality objectives.

A programme for conducting internal audits needs to be prepared applying risk-based thinking and taking into account the result of previous audits, management reviews, complaints, nonconformities and business action plans. Audits should be conducted both at the organizational level and the project level. The firm needs to decide the appropriate sampling and frequency of project audits within the internal audit programme.

An audit should comprise the following key phases:

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- **Planning.** The auditor familiarises himself or herself with the subject to be audited. An audit plan and a checklist of questions to be prepared
- **Conducting.** The auditor seeks evidence to each of the pre-planned checklist questions
- **Reporting.** The auditor reviews the results, and reports the findings to the management controlling the work under audit
- **Follow-up and verification of actions taken.** Management responsible for the audited area should ensure that the actions taken to eliminate the causes of nonconformities are effective, and that results are recorded.

Audits need to be carried out by someone who can be objective and impartial.

The firm needs to retain documented information of the audit programme and audit results.

See ISO 19011 for guidance.

#### **Standard**

##### 9.3 Management review

#### **Purpose**

To provide a strategic assessment of the QMS as a basis for ensuring its continuing suitability, adequacy and effectiveness.

#### **Guidance**

Top management needs to lead the management review process and not delegate it to persons who do not have the authority to commit the firm to action.

Large firms need to consider having a management review process which “cascades up”, having sectional, divisional and corporate reviews. Large projects may need their own management review programme as a part of their management strategy, bringing together the client and other parties involved in the project.

In most consulting engineering firms, management review can be conducted effectively in any meeting, with the decisions and the actions to be taken recorded in the minutes. It is the intention that the management review process is integral to the business management of an organization. It is

therefore useful to align management reviews with the business cycle, so that outputs of the review can be used in wider business planning

The intervals at which management reviews of the QMS are to be conducted should be defined. The management reviews may be more frequent during periods of development or change of the QMS, or at other times, such as a change in key personnel or the nature of the firm, following a significant client complaint.

As well as reviewing evidence concerning the adequacy of the QMS, the quality of deliverables and the achievement of client satisfaction, it is very important for a consulting engineering firm to consider the issue of personnel training, and how the firm is to maintain capability for the work it does and plans to do. Reviews should assess the effectiveness of training and the benefits derived for projects, the practice, personnel and clients. The adequacy of physical resources and facilities should also be included in management reviews.

As a rule of thumb, amendment of the management system need be considered with every change in the business model of the firm, with new classes of clients, or new building technology (such as BIM).

The decisions and actions arising out of management review process need to be retained as documented information. The firm may decide on the format of the documented information. The firm may also retain further documented information at its discretion.

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## **Ch. 10 – Improvement**

#### **Standard**

##### 10.1 General

#### **Purpose**

To improve customer satisfaction and the performance of the firm through a systematic approach, using opportunities from both the results of evaluation and review, and lessons learnt from the correction and analysis of problems.

#### **Guidance**

It is generally accepted that to stay ahead, processes and practices need to be continually improved to meet changing expectations, both from the client and the consulting engineering firm itself. Achieving this requires persistent

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assessment of performance through collection and analysis of data, a consistent process to learn from correcting and avoiding errors, development and implementation of improvement initiatives, and the assessment of how effective those initiatives have been.

#### **Standard**

#### 10.2 Nonconformity and corrective action

#### **Purpose**

To correct, prevent or reduce undesired effects

#### **Guidance**

Consulting engineering firms need to take action to reduce the likelihood of recurrence or occurrence elsewhere of product and service nonconformities and nonconformities in management processes, whether identified during audits or through other means. The firm also needs a process to deal with complaints from clients and other interested parties, whether or not such complaints relate to nonconformity of products and services.

One of the most challenging situations is where a nonconformity is detected after delivery of a service and correction cannot be carried out to prevent future error, for example identification of a design error (by the firm itself or an external party) where construction has been completed. In such cases, considerations such as duty of care, legal aspects and redesign and repair options need to be taken into account in the corrective action process.

The requirements of clause 10.2 on non-conformity and corrective action are largely self-explanatory.

For more information on complaints management refer to ISO 10002.

#### **Standard**

#### 10.3 Continual Improvement

#### **Purpose**

To maintain commitment to continually improving the firm's QMS.

#### **Guidance**

The outputs of analysis and evaluation (see clause 9.1.3), internal and external audits, client evaluations and management reviews may be used to identify opportunities for improvement. The firm needs to be able to show evidence of efforts to improve the effectiveness of the QMS. This may be done through specific initiatives undertaken to meet quality objectives both at the organizational level and at the project level and/or by changing the quality policy and the quality objectives.

Various quality tools are available for continual improvement, including Pareto Analysis, Six Sigma, Value Engineering, Fishbone/Ishikawa diagrams, 5 Whys etc. It is up to firm to decide which of these tools will be appropriate for their continual improvement efforts.

## BIBLIOGRAPHY - REFERENCES AND FURTHER READING

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- *ISO 9004, Organizational quality – Guidance to achieve sustained success*<sup>1</sup>
- *ISO 10002, Quality management – Customer satisfaction – Guidelines for complaints handling in organizations*
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<sup>1</sup> In revision at time of publication of this Guide

<sup>2</sup> Available from website: <http://www.iso.org>.



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