- **Page 1** FINAL DRAFT INTERNATIONAL STANDARD ISO/FDIS 9001 ISO/TC 176/SC 2 Secretariat: BSI Voting begins on: 2015-07-09 Voting terminates on: 2015-09-09 Quality management systems - Requirements Systèmes de management de la qualité - Exigences RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION. IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS. Please see the administrative notes on page iii ISO Reference number ISO/FDIS 9001:2015(E) ISO 2015

- **Page 2** ISO/FDIS 9001:2015(E) ISO/CEN PARALLEL PROCESSING This final draft has been developed within the International Organization for Standardization (ISO), and processed under the ISO-lead mode of collaboration as defined in the Vienna Agreement. The final draft was established on the basis of comments received during a parallel enquiry on the draft. This final draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel two-month approval vote in ISO and formal vote in CEN. Positive votes shall not be accompanied by comments. Negative votes shall be accompanied by the relevant technical reasons.

- **Page 5** ISO/FDIS 9001:2015(E) Foreword ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization. The procedures used to develop this document and those intended

for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives). Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents). Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement. For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html. The committee responsible for this document is Technical Committee ISO/TC 176, Quality management and quality assurance, Subcommittee SC 2, Quality systems. This fifth edition cancels and replaces the fourth edition (ISO 9001:2008), which has been technically revised, through the adoption of a revised clause sequence and the adaptation of the revised quality management principles and of new concepts. ISO 2015-All rights reserved v

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- **Page 6** ISO/FDIS 9001:2015(E) Introduction 0.1 General The adoption of a quality management system is a strategic decision for an organization that can help to improve its overall performance and provide a sound basis for sustainable development initiatives. The potential benefits to an organization of implementing a quality management system based on this International Standard are: a) the ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements; b) facilitating opportunities to enhance customer satisfaction; c) addressing risks and opportunities associated with its context and objectives; d) the ability to demonstrate conformity to specified quality management system requirements. This International Standard can be used by internal and external parties. It is not the intent of this International Standard to imply the need for: uniformity in the structure of different quality management systems; alignment of documentation to the clause structure of this International Standard; the use of the specific terminology of this International Standard within the organization. The quality management system requirements specified in this International Standard are complementary to requirements for products and services. This International Standard employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking. The process approach enables an organization to plan its processes and their

interactions. The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are determined and acted on. Risk-based thinking enables an organization to determine the factors that could cause its processes and its quality management system to deviate from the planned results, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise (see Clause A.4). Consistently meeting requirements and addressing future needs and expectations poses a challenge for organizations in an increasingly dynamic and complex environment. To achieve this objective, the organization might find it necessary to adopt various forms of improvement in addition to correction and continual improvement, such as breakthrough change, innovation and re-organization. In this International Standard, the following verbal forms are used: "shall" indicates a requirement; "should" indicates a recommendation; "may" indicates a permission; "can" indicates a possibility or a capability. Information marked as "NOTE" is for guidance in understanding or clarifying the associated requirement. vi ISO 2015-All rights reserved

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- **Page 7** ISO/FDIS 9001:2015(E) 0.2 Quality management principles This International Standard is based on the quality management principles described in ISO 9000. The descriptions include a statement of each principle, a rationale of why the principle is important for the organization, some examples of benefits associated with the principle and examples of typical actions to improve the organization's performance when applying the principle. The quality management principles are: customer focus; leadership; engagement of people; process approach; improvement; evidence-based decision making; relationship management. 0.3 Process approach 0.3.1 General This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements. Specific requirements considered essential to the adoption of a process approach are included in 4.4. Understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its intended results. This approach enables the organization to control the interrelationships and interdependencies among the processes of the system, so that the overall performance of the organization can be enhanced. The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using the PDCA cycle (see 0.3.2) with an overall focus on risk-based thinking (see 0.3.3) aimed at taking advantage of opportunities and preventing undesirable results. The application of the process approach in a quality

management system enables: a) understanding and consistency in meeting requirements; b) the consideration of processes in terms of added value; c) the achievement of effective process performance; d) improvement of processes based on evaluation of data and information. Figure 1 gives a schematic representation of any process and shows the interaction of its elements. The monitoring and measuring checkpoints, which are necessary for control, are specific to each process and will vary depending on the related risks. ISO 2015-All rights reserved vii

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- **Page 9** ISO/FDIS 9001:2015(E) The PDCA cycle can be briefly described as follows: Plan: establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and the organization's policies; Do: implement what was planned; Check: monitor and (where applicable) measure processes and the resulting products and services against policies, objectives and requirements and report the results; Act: take actions to improve performance, as necessary. 0.3.3 Risk-based thinking Risk-based thinking (see Clause A.4) is essential for achieving an effective quality management system. The concept of risk-based thinking has been implicit in previous editions of this International Standard including, for example, carrying out preventive action to eliminate potential nonconformities, analysing any nonconformities that do occur, and taking action to prevent recurrence that is appropriate for the effects of the nonconformity. To conform to the requirements of this International Standard, an organization needs to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the quality management system, achieving improved results and preventing negative effects. Opportunities can arise as a result of a situation favourable to achieving an intended result, for example, a set of circumstances that allow the organization to attract customers, develop new products and services, reduce waste or improve productivity. Actions to address opportunities can also include consideration of associated risks. Risk is the effect of uncertainty and any such uncertainty can have positive or negative effects. A positive deviation arising from a risk can provide an opportunity, but not all positive effects of risk result in opportunities. 0.4 Relationship with other management system standards This International Standard applies the framework developed by ISO to improve alignment among its International Standards for management systems (see Clause A.1). This International Standard enables an organization to use the process approach, coupled with the PDCA cycle and risk-based thinking, to align or integrate its quality management system with the requirements of other management system standards. This International Standard relates to ISO 9000 and ISO 9004 as follows: ISO 9000 Quality management systems - Fundamentals and vocabulary provides essential background for the proper understanding and implementation of this

International Standard; ISO 9004 Managing for the sustained success of an organization - A quality management approach provides guidance for organizations that choose to progress beyond the requirements of this International Standard. Annex B provides details of other International Standards on quality management and quality management systems that have been developed by ISO/TC 176. This International Standard does not include requirements specific to other management systems, such as those for environmental management, occupational health and safety management, or financial management. Sector-specific quality management system standards based on the requirements of this International Standard have been developed for a number of sectors. Some of these standards specify additional quality management system requirements, while others are limited to providing guidance to the application of this International Standard within the particular sector. ISO 2015-All rights reserved ix

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- **Page 10** ISO/FDIS 9001:2015(E) A matrix showing the correlation between the clauses of this edition of this International Standard and the previous edition (ISO 9001:2008) can be found on the ISO/TC 176/SC 2 open access web site at: www.iso.org/tc176/sc02/public. X ISO 2015-All rights reserved

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- **Page 11** FINAL DRAFT INTERNATIONAL STANDARD ISO/FDIS 9001:2015(E) Quality management systems - Requirements 1 Scope This International Standard specifies requirements for a quality management system when an organization: a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements. All the requirements of this International Standard are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides. NOTE 1 In this International Standard, the terms "product" or "service" only apply to products and services intended for, or required by, a customer. NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements. 2 Normative references The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. ISO 9000:2015, Quality management systems - Fundamentals and vocabulary 3 Terms and definitions For the purposes of this document, the terms and definitions given in ISO 9000:2015 apply. 4 Context of the organization 4.1

Understanding the organization and its context The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system. The organization shall monitor and review information about these external and internal issues. NOTE 1 Issues can include positive and negative factors or conditions for consideration. NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local. NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization. ISO 2015-All rights reserved 1

- **Page 12** ISO/FDIS 9001:2015(E) 4.2 Understanding the needs and expectations of interested parties Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine: a) the interested parties that are relevant to the quality management system; b) the requirements of these interested parties that are relevant to the quality management system. The organization shall monitor and review information about these interested parties and their relevant requirements. 4.3 Determining the scope of the quality management system The organization shall determine the boundaries and applicability of the quality management system to establish its scope. When determining this scope, the organization shall consider: a) the external and internal issues referred to in 4.1; b) the requirements of relevant interested parties referred to in 4.2; c) the products and services of the organization. The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system. The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system. Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction. 4.4 Quality management system and its processes 4.4.1 The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard. The organization shall determine the processes needed for the quality management system and their application throughout the organization,

and shall: a) determine the inputs required and the outputs expected from these processes; b) determine the sequence and interaction of these processes; c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes; d) determine the resources needed for these processes and ensure their availability; e) assign the responsibilities and authorities for these processes; f) address the risks and opportunities as determined in accordance with the requirements of 6.1; g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results; 2 ISO 2015-All rights reserved

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- **Page 13** ISO/FDIS 9001:2015(E) h) improve the processes and the quality management system. 4.4.2 To the extent necessary, the organization shall: a) maintain documented information to support the operation of its processes; b) retain documented information to have confidence that the processes are being carried out as planned. 5 Leadership 5.1 Leadership and commitment 5.1.1 General Top management shall demonstrate leadership and commitment with respect to the quality management system by: a) taking accountability for the effectiveness of the quality management system; b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization; c) ensuring the integration of the quality management system requirements into the organization's business processes; d) promoting the use of the process approach and risk-based thinking; e) ensuring that the resources needed for the quality management system are available; f) communicating the importance of effective quality management and of conforming to the quality management system requirements; g) ensuring that the quality management system achieves its intended results; h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system; i) promoting improvement; j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility. NOTE Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit. 5.1.2 Customer focus Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that: a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met; b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed; c) the focus on enhancing customer satisfaction is maintained. ISO 2015-All rights reserved 3

- **Page 14** ISO/FDIS 9001:2015(E) 5.2 Policy 5.2.1 Developing the quality policy Top management shall establish, implement and maintain a quality policy that: a) is appropriate to the purpose and context of the organization and supports its strategic direction; b) provides a framework for setting quality objectives; c) includes a commitment to satisfy applicable requirements; d) includes a commitment to continual improvement of the quality management system. 5.2.2 Communicating the quality policy The quality policy shall: a) be available and be maintained as documented information; b) be communicated, understood and applied within the organization; c) be available to relevant interested parties, as appropriate. 5.3 Organizational roles, responsibilities and authorities Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization. Top management shall assign the responsibility and authority for: a) ensuring that the quality management system conforms to the requirements of this International Standard; b) ensuring that the processes are delivering their intended outputs; c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management; d) ensuring the promotion of customer focus throughout the organization; e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented. 6 Planning 6.1 Actions to address risks and opportunities 6.1.1 When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to: a) give assurance that the quality management system can achieve its intended result(s); b) enhance desirable effects; c) prevent, or reduce, undesired effects; d) achieve improvement. 4 ISO 2015-All rights reserved

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- **Page 15** ISO/FDIS 9001:2015(E) 6.1.2 The organization shall plan: a) actions to address these risks and opportunities; b) how to:

    1. integrate and implement the actions into its quality management system processes (see 4.4);
    2. evaluate the effectiveness of these actions. Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services. NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision. NOTE 2 Opportunities can lead

to the adoption of new practices, launching new products, opening new markets, addressing new clients, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs. 6.2 Quality objectives and planning to achieve them 6.2.1 The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system. The quality objectives shall: a) be consistent with the quality policy; b) be measurable; c) take into account applicable requirements; d) be relevant to conformity of products and services and to enhancement of customer satisfaction; e) be monitored; f) be communicated; g) be updated as appropriate. The organization shall maintain documented information on the quality objectives. 6.2.2 When planning how to achieve its quality objectives, the organization shall determine: a) what will be done; b) what resources will be required; c) who will be responsible; d) when it will be completed; e) how the results will be evaluated. 6.3 Planning of changes When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4). ISO 2015-All rights reserved 5

- **Page 16** ISO/FDIS 9001:2015(E) The organization shall consider: a) the purpose of the changes and their potential consequences; b) the integrity of the quality management system; c) the availability of resources; d) the allocation or reallocation of responsibilities and authorities. 7 Support 7.1 Resources 7.1.1 General The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system. The organization shall consider: a) the capabilities of, and constraints on, existing internal resources; b) what needs to be obtained from external providers. 7.1.2 People The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes. 7.1.3 Infrastructure The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. NOTE Infrastructure can include: a) buildings and associated utilities; b) equipment, including hardware and software; c) transportation resources; d) information and communication technology. 7.1.4 Environment for the operation of processes The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services. NOTE A suitable environment can be a combination of human and physical factors, such as: a) social (e.g. non-discriminatory, calm, non-confrontational); b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective); c)

physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise). These factors can differ substantially depending on the products and services provided. 6 ISO 2015-All rights reserved

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- **Page 17** ISO/FDIS 9001:2015(E) 7.1.5 Monitoring and measuring resources 7.1.5.1 General The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements. The organization shall ensure that the resources provided: a) are suitable for the specific type of monitoring and measurement activities being undertaken; b) are maintained to ensure their continuing fitness for their purpose. The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources. 7.1.5.2 Measurement traceability When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be: a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information; b) identified in order to determine their status; c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results. The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary. 7.1.6 Organizational knowledge The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge shall be maintained and be made available to the extent necessary. When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates. NOTE 1 Organizational knowledge is knowledge specific to the organization; it is gained by experience. It is information that is used and shared to achieve the organization's objectives. NOTE 2 Organizational knowledge can be based on: a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services); b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers). 7.2 Competence The organization shall: a) determine the necessary competence of person(s) doing work under its control that affects the

performance and effectiveness of the quality management system; ISO 2015-All rights reserved 7

- **Page 18** ISO/FDIS 9001:2015(E) b) ensure that these persons are competent on the basis of appropriate education, training, or experience; c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken; d) retain appropriate documented information as evidence of competence. NOTE Applicable actions can include, for example, the provision of training to, the mentoring of, or the re-assignment of currently employed persons; or the hiring or contracting of competent persons. 7.3 Awareness The organization shall ensure that persons doing work under the organization's control are aware of: a) the quality policy; b) relevant quality objectives; c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance; d) the implications of not conforming with the quality management system requirements. 7.4 Communication The organization shall determine the internal and external communications relevant to the quality management system, including: a) on what it will communicate; b) when to communicate; c) with whom to communicate; d) how to communicate; e) who communicates. 7.5 Documented information 7.5.1 General The organization's quality management system shall include: a) documented information required by this International Standard; b) documented information determined by the organization as being necessary for the effectiveness of the quality management system. NOTE The extent of documented information for a quality management system 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 persons. 8 ISO 2015-All rights reserved

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- **Page 19** ISO/FDIS 9001:2015(E) 7.5.2 Creating and updating When creating and updating documented information, the organization shall ensure appropriate: a) identification and description (e.g. a title, date, author, or reference number); b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic); c) review and approval for suitability and adequacy. 7.5.3 Control of documented information 7.5.3.1 Documented information required by the quality management system and by this International Standard shall be controlled to ensure: a) it is available and suitable for use, where and when it is needed; b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity). 7.5.3.2 For the control of documented information, the organization shall address the following activities, as applicable: a) distribution, access, retrieval and use; b) storage and preservation, including preservation of legibility; c) control of changes (e.g.

version control); d) retention and disposition. Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and be controlled. Documented information retained as evidence of conformity shall be protected from unintended alterations. NOTE Access 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. 8 Operation 8.1 Operational planning and control The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by: a) determining the requirements for the products and services; b) establishing criteria for:

1. the processes;
2. the acceptance of products and services; c) determining the resources needed to achieve conformity to the product and service requirements; d) implementing control of the processes in accordance with the criteria; e) determining and keeping documented information to the extent necessary:
3. to have confidence that the processes have been carried out as planned; ISO 2015-All rights reserved 9

- **Page 20** ISO/FDIS 9001:2015(E) 2) to demonstrate the conformity of products and services to their requirements. NOTE "Keeping" implies both the maintaining and the retaining of documented information. The output of this planning shall be suitable for the organization's operations. The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. The organization shall ensure that outsourced processes are controlled (see 8.4). 8.2 Requirements for products and services 8.2.1 Customer communication Communication with customers shall include: a) providing information relating to products and services; b) handling enquiries, contracts or orders, including changes; c) obtaining customer feedback relating to products and services, including customer complaints; d) handling or controlling customer property; e) establishing specific requirements for contingency actions, when relevant. 8.2.2 Determining the requirements related to products and services When determining the requirements for the products and services to be offered to customers, the organization shall ensure that: a) the requirements for the products and services are defined, including:

    1. any applicable statutory and regulatory requirements;

2. those considered necessary by the organization; b) the organization can meet the claims for the products and services it offers. 8.2.3 Review of requirements related to products and services 8.2.3.1 The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to a customer, to include: a) requirements specified by the customer, including the requirements for delivery and post-delivery activities; b) requirements not stated by the customer, but necessary for the specified or intended use, when known; c) requirements specified by the organization; d) statutory and regulatory requirements applicable to the products and services; e) contract or order requirements differing from those previously expressed. The organization shall ensure that contract or order requirements differing from those previously defined are resolved. 10 ISO 2015-All rights reserved

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- **Page 21** ISO/FDIS 9001:2015(E) The customer's requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements. NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues or advertising material. 8.2.3.2 The organization shall retain documented information, as applicable: a) on the results of the review; b) on any new requirements for the products and services. 8.2.4 Changes to requirements for products and services The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed. 8.3 Design and development of products and services 8.3.1 General The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services. 8.3.2 Design and development planning In determining the stages and controls for design and development, the organization shall consider: a) the nature, duration and complexity of the design and development activities; b) the required process stages, including applicable design and development reviews; c) the required design and development verification and validation activities; d) the responsibilities and authorities involved in the design and development process; e) the internal and external resource needs for the design and development of products and services; f) the need to control interfaces between persons involved in the design and development process; g) the need for involvement of customers and users in the design and development process; h) the requirements for subsequent provision of products and services; i) the level of control expected for the design and development process by customers and other relevant interested parties; j) the

documented information needed to demonstrate that design and development requirements have been met. 8.3.3 Design and development inputs The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider: a) functional and performance requirements; b) information derived from previous similar design and development activities; c) statutory and regulatory requirements; ISO 2015-All rights reserved 11

- **Page 22** ISO/FDIS 9001:2015(E) d) standards or codes of practice that the organization has committed to implement; e) potential consequences of failure due to the nature of the products and services. Inputs shall be adequate for design and development purposes, complete and unambiguous. Conflicting design and development inputs shall be resolved. The organization shall retain documented information on design and development inputs. 8.3.4 Design and development controls The organization shall apply controls to the design and development process to ensure that: a) the results to be achieved are defined; b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements; c) verification activities are conducted to ensure that the design and development outputs meet the input requirements; d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use; e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities; f) documented information of these activities is retained. NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization. 8.3.5 Design and development outputs The organization shall ensure that design and development outputs: a) meet the input requirements; b) are adequate for the subsequent processes for the provision of products and services; c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria; d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision. The organization shall retain documented information on design and development outputs. 8.3.6 Design and development changes The organization shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements. The organization shall retain documented information on: a) design and development changes; b) the results of reviews; c) the authorization of the changes; d) the actions taken to prevent adverse impacts. 12 ISO 2015-All rights reserved

- **Page 23** ISO/FDIS 9001:2015(E) 8.4 Control of externally provided processes, products and services 8.4.1 General The organization shall ensure that externally provided processes, products and services conform to requirements. The organization shall determine the controls to be applied to externally provided processes, products and services when: a) products and services from external providers are intended for incorporation into the organization's own products and services; b) products and services are provided directly to the customer(s) by external providers on behalf of the organization; c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization. The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The organization shall retain documented information of these activities and any necessary actions arising from the evaluations. 8.4.2 Type and extent of control The organization shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers. The organization shall: a) ensure that externally provided processes remain within the control of its quality management system; b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output; c) take into consideration:

    1. 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;
    2. the effectiveness of the controls applied by the external provider; d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements. 8.4.3 Information for external providers The organization shall ensure the adequacy of requirements prior to their communication to the external provider. The organization shall communicate to external providers its requirements for: a) the processes, products and services to be provided; b) the approval of:
    3. products and services;
    4. methods, processes and equipment; ISO 2015-All rights reserved 13

- **Page 24** ISO/FDIS 9001:2015(E) 3) the release of products and services; c) competence, including any required qualification of persons; d) the external providers' interactions with the organization; e) control and monitoring of the external providers' performance to be applied by the organization; f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises. 8.5 Production and service provision 8.5.1 Control of production and service provision The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable: a) the availability of documented information that defines:
    1. the characteristics of the products to be produced, the services to be provided, or the activities to be performed;
    2. the results to be achieved; b) the availability and use of suitable monitoring and measuring resources; c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met; d) the use of suitable infrastructure and environment for the operation of processes; e) the appointment of competent persons, including any required qualification; f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement; g) the implementation of actions to prevent human error; h) the implementation of release, delivery and post-delivery activities. 8.5.2 Identification and traceability The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services. The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision. The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability. 8.5.3 Property belonging to customers or external providers The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services. 14 ISO 2015-All rights reserved

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- **Page 25** ISO/FDIS 9001:2015(E) When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain

documented information on what has occurred. NOTE A customer's or external provider's property can include material, components, tools and equipment, premises, intellectual property and personal data. 8.5.4 Preservation The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements. NOTE Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection. 8.5.5 Post-delivery activities The organization shall meet requirements for post-delivery activities associated with the products and services. In determining the extent of post-delivery activities that are required, the organization shall consider: a) statutory and regulatory requirements; b) the potential undesired consequences associated with its products and services; c) the nature, use and intended lifetime of its products and services; d) customer requirements; e) customer feedback. NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal. 8.5.6 Control of changes The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements. The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review. 8.6 Release of products and services The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met. The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer. The organization shall retain documented information on the release of products and services. The documented information shall include: a) evidence of conformity with the acceptance criteria; b) traceability to the person(s) authorizing the release. ISO 2015-All rights reserved 15

- **Page 26** ISO/FDIS 9001:2015(E) 8.7 Control of nonconforming outputs 8.7.1 The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery. The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services. The organization shall deal with nonconforming outputs in one or more of the following ways: a) correction; b) segregation, containment, return or suspension of provision of products and services; c) informing the customer; d) obtaining authorization for acceptance under concession. Conformity to the requirements shall be verified when nonconforming outputs are

corrected. 8.7.2 The organization shall retain documented information that: a) describes the nonconformity; b) describes the actions taken; c) describes any concessions obtained; d) identifies the authority deciding the action in respect of the nonconformity. 9 Performance evaluation 9.1 Monitoring, measurement, analysis and evaluation 9.1.1 General The organization shall determine: a) what needs to be monitored and measured; b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results; c) when the monitoring and measuring shall be performed; d) when the results from monitoring and measurement shall be analysed and evaluated. The organization shall evaluate the performance and the effectiveness of the quality management system. The organization shall retain appropriate documented information as evidence of the results. 9.1.2 Customer satisfaction The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring and reviewing this information. NOTE Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports. 16 ISO 2015-All rights reserved

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- **Page 27** ISO/FDIS 9001:2015(E) 9.1.3 Analysis and evaluation The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement. The results of analysis shall be used to evaluate: a) conformity of products and services; b) the degree of customer satisfaction; c) the performance and effectiveness of the quality management system; d) if planning has been implemented effectively; e) the effectiveness of actions taken to address risks and opportunities; f) the performance of external providers; g) the need for improvements to the quality management system. NOTE Methods to analyse data can include statistical techniques. 9.2 Internal audit 9.2.1 The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system: a) conforms to:

    1. the organization's own requirements for its quality management system;
    2. the requirements of this International Standard; b) is effectively implemented and maintained. 9.2.2 The organization shall: a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits; b) define the audit criteria and scope for each audit; c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process; d) ensure that the

results of the audits are reported to relevant management; e) take appropriate correction and corrective actions without undue delay; f) retain documented information as evidence of the implementation of the audit programme and the audit results. NOTE See ISO 19011 for guidance. ISO 2015-All rights reserved 17

- **Page 28** ISO/FDIS 9001:2015(E) 9.3 Management review 9.3.1 General Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization. 9.3.2 Management review inputs The management review shall be planned and carried out taking into consideration: a) the status of actions from previous management reviews; b) changes in external and internal issues that are relevant to the quality management system; c) information on the performance and effectiveness of the quality management system, including trends in:
    1. customer satisfaction and feedback from relevant interested parties;
    2. the extent to which quality objectives have been met;
    3. process performance and conformity of products and services;
    4. nonconformities and corrective actions;
    5. monitoring and measurement results;
    6. audit results;
    7. the performance of external providers; d) the adequacy of resources; e) the effectiveness of actions taken to address risks and opportunities (see 6.1); f) opportunities for improvement. 9.3.3 Management review outputs The outputs of the management review shall include decisions and actions related to: a) opportunities for improvement; b) any need for changes to the quality management system; c) resource needs. The organization shall retain documented information as evidence of the results of management reviews. 10 Improvement 10.1 General The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction. 18 ISO 2015-All rights reserved

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- **Page 29** ISO/FDIS 9001:2015(E) These shall include: a) improving products and services to meet requirements as well as to address future needs and expectations; b) correcting, preventing or reducing undesired effects; c) improving the

performance and effectiveness of the quality management system. NOTE Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization. 10.2 Nonconformity and corrective action 10.2.1 When a nonconformity occurs, including any arising from complaints, the organization shall: a) react to the nonconformity and, as applicable:

1. take action to control and correct it;
2. deal with the consequences; b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
3. reviewing and analysing the nonconformity;
4. determining the causes of the nonconformity;
5. determining if similar nonconformities exist, or could potentially occur; c) implement any action needed; d) review the effectiveness of any corrective action taken; e) update risks and opportunities determined during planning, if necessary; f) make changes to the quality management system, if necessary. Corrective actions shall be appropriate to the effects of the nonconformities encountered. 10.2.2 The organization shall retain documented information as evidence of: a) the nature of the nonconformities and any subsequent actions taken; b) the results of any corrective action. 10.3 Continual improvement The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system. The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement. ISO 2015-All rights reserved 19

ISO 9001:2015 QUALITY MANAGEMENT SYSTEMS – REQUIREMENTS Guidance Document Page 1 DNV GL AS, NO-1322 Høvik, Norway, Tel: +47 67 57 99 00, www.dnvgl.com Version 24.09.15 Introduction This DNV GL guidance document aims to gives a basic overview of the changes to ISO 9001, resulting from the review and revision of the 2008 standard. It is not intended to give an exhaustive and in-depth explanation of all requirements in the new standard. ISO standards are reviewed and revised on a regular cycle, typically every 5-10 years, and 2015 sees ISO 9001:2008 reaching the end of that review process. A draft international standard (DIS) was published, and after extensive review the inital draft international standard (FDIS) was published in July. The ISO 9001:2015 standard was published in September 2015. The International Standards Organization (ISO) has developed a common Higher Level Structure (HLS) for management system standards, issued under an ISO Directive; http://www.iso.org/sites/directives/directives.html That directive has a series of annexes, of which we are interested in “Annex SL – Proposals for management systems

standards". This annex states that all management system standards will use a consistent structure, common text and terminology, and this is enacted through "Appendix 2 – High level structure, identical core text, common terms and core deinitions". Some revised and new standards have already implemented this requirement – for example ISO 27001:2013 Information Security Management Systems (revised) and ISO 55001:2014 Asset Management Standard (new). ISO 9001 has been revised in accordance with the new HLS and, as is the case with other HLS-based standards, it also contains additional disciplinespeciic content. A whole range of country-level committees feed into the overall ISO committees which meet to decide on the revisions. The committee for ISO 9001 is TC 176. If you are a member of IRCA, or a trade federation, you can get access to the latest version of the draft Standard(s) and even comment on the content. After the new standards are published, there will be a transition period for fully complying with them. This period will be 3 years, but it is strongly recommended that you start thinking now about how it will impact you, and review what changes might be needed. How we can help We are here to support you during the transition, through; ■ direct contact, e.g. with your lead auditor as part of scheduled audits ■ open webinars and transition training ■ classroom transition training courses – tailored to your needs ■ gap analysis, either as a separate activity or combined with scheduled audit activity ■ combination of training and gap analysis ■ "Questions on the ISO 9001:2015 and ISO 14001:2015 revisions" – LinkedIn discussion group Page 2 DNV GL AS, NO-1322 Høvik, Norway, Tel: +47 67 57 99 00, www.dnvgl.com Version 24.09.15 Layout of ISO 9001:2015 1 Scope 2 Normative References 3 Terms and deinitions 4 Context of the organization 4.1 Understanding the organization and its context 4.2 Understanding the needs and expectations of interested parties 4.3 Determining the scope of the quality management system 4.4 Quality management system and its processes 5 Leadership 5.1 Leadership and commitment 5.2 Policy 5.3 Organizational roles, responsibilities and authorities 6 Planning 6.1 Actions to address risks and opportunities 6.2 Quality objectives and planning to achieve them 6.3 Planning of changes 7 Support 7.1 Resources 7.2 Competence 7.3 Awareness 7.4 Communication 7.5 Documented information 8 Operation 8.1 Operational planning and control 8.2 Requirements for products and services 8.3 Design and development of products and services 8.4 Control of externally provided processes, products and services 8.5 Production and service provision 8.6 Release of products and services 8.7 Control of nonconforming outputs. 9 Performance evaluation 9.1 Monitoring, measurement, analysis and evaluation 9.2 Internal audit 9.3 Management review 10 Improvement 10.1 General 10.2 Nonconformity and corrective action 10.3 Continual improvement Page 3 DNV GL AS, NO-1322 Høvik, Norway, Tel: +47 67 57 99 00, www.dnvgl.com Version 24.09.15 1. Scope This section explains the scope of the standard – i.e. what it is for and what it encompasses. It introduces the requirements of a quality management system which supports the delivery of a product or service, through the application of effective and continually improving systems, assuring conformity to customer and applicable legal requirements, whilst enhancing customer satisfaction. The section on "Application" in ISO 9001:2008 has been dropped, along with reference to "exclusions" (see

ISO 9001:2015 clause 4.3). 2. Normative references ISO 9000:2015, Quality management systems — Fundamentals and vocabulary is normatively referenced within ISO 9001:2015. 3. Terms and definitions This clause simply references back to ISO 9000:2015 (see clause 2). 4. Context of the organization This clause sets out the requirements for an organization to take a high level overview of the business, considering the key internal and external factors which impact it, and how it should respond in the form of a deined management system. 4.1 Understanding the organization and its context This clause requires the organization to consider a wide range of potential factors which can impact on the management system, in terms of its structure, scope, implementation and operation. Impacting factors can be of internal or external nature, and are wide-ranging; n External factors can arise from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local. n Internal factors may be related to values, culture, knowledge and performance of the organization. 4.2 Understanding the needs and expectations of interested parties Clause 4.2 requires the organization to determine the need and expectations of “interested parties”, both internal and external. Previous versions of the draft standard also contained the term “stakeholder”, which many organizations will be more familiar with – the terms are synonymous and there is no need to consider them to be any different. Interested parties could include; n Employees n Contractors n Clients/Customers n Suppliers n Regulators n Shareholders n Neighbours n NonGovernmental Organizations (NGOs) n Parent organizations What is clear is that whilst the consideration of context and interested parties needs to be relevant to the scope and the standard, the assessment needs to be appropriate and proportionate. Page 4 DNV GL AS, NO-1322 Høvik, Norway, Tel: +47 67 57 99 00, www.dnvgl.com Version 24.09.15 What is also clear is that the output from clauses 4.1 and 4.2 is a key input to the assessment and determination of risks and opportunities required in clause 6. In terms of demonstrating compliance, the ISO 9001 makes it clear that; “The organization shall monitor and review the information about these external and internal issues” (clause 4.1). “The organization shall monitor and review the information about these interested parties and their relevant requirements” (clause 4.2). The above implies that there will need to be some form of retained documented information of this to evidence how internal and external factors and the views of interested parties have been considered. There are various methods and approaches which can be used to capture these inputs. As with any signiicant revision to standards, hopefully there will be the development of a range of methods and examples for this. Some current examples include; Internal and External Issues n Key economic and market development which can impact on the organization; your organization is probably acutely aware of what is happening in its markets but it may be undertaken in a very ad-hoc way n Technological innovations and developments; this is also an area critical to your business success and is also probably being monitored and discussed at numerous levels n Regulatory developments; a whole range of external regulations are being monitored by your organization. If you miss them then it could seriously damage your business, or if you capture early intelligence on them you could realize better opportunities n Political and

other instabilities; if for example you rely on raw materials from one particular country which experiences major instability your whole business could be jeopardized; or if there are major ethical concerns regarding a source of materials or goods n Organizational culture and attitudes; an effective and motivated workforce will give you positive impacts, and many organizations canvas feedback from employees Internal and External Parties n Stakeholder engagement exercises; already widely used to consult with interested parties and map out concerns and issues. More often utilized by larger organizations engaging with corporate social responsibility initiatives n Consultation meetings with neighbourhoods and NGOs on environment, planning and development issues; these are often used by major industrial plants with signiicant HSE risks n Meetings and other interactions with regulators; this can encompass for example quality-critical issues on product speciications and conformity as well as developing compliance requirements and standards n Employee meetings, consultations and feedback activities; this should be happening already, but maybe this will prompt more efforts to improve an area which has been at risk of “lip service” to ISO 9001:2008 n Supplier reviews and relationship management; many organizations are trying to get much more mutual beneit from the supplier-client relationships which are critical to mutual success n Client/customer reviews and relationship management; of course this is a fundamental pillar of all standards and a key to success n It may be that when you relect on how you capture key issues, and how many interested parties you engage with already you may be pleasantly surprised. It may be that you only engage with a limited number of internal and external parties, but now is the time to start thinking about whether that is enough, and whether you are missing some good opportunities. There will be many ways in which to capture this – and hopefully some improved and new approaches might emerge as this part of the standard is considered. Approaches could include; n Summary information from the range of existing approaches used as listed above (e.g. a brief report) n Information summarized as part of inputs to risk and opportunity registers n Recorded in a simple spreadsheet n Logged and maintained in a database n Captured and recorded through key meetings These clauses are asking organizations to think clearly and logically about what can internally and externally affect their management systems, and be in a position to show that this information is being monitored and reviewed. It also requires organizations to elevate the discussions to the highest levels, since capturing the above range of information is hard to achieve without senior management involvement. Page 5 DNV GL AS, NO-1322 Høvik, Norway, Tel: +47 67 57 99 00, www.dnvgl.com Version 24.09.15 4.3 Determining the scope of the quality management system This clause should be familiar to most organizations, since ISO 9001:2008 clause 4.2.2 required the deinition of the scope of the management system. For ISO 9001:2015 the scoping requirements have become more stringent and require the organization to consider the inputs from 4.1 and 4.2, along with the products and services being delivered. For the deined scope of the quality management system, the organisation should apply all requirements of the standard if they are applicable. When any requirement is not applicable there needs to be a clear justiication. The deined scope has to be made available and maintained as documented information. The standard states,

‘Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization’s ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction’. These clearer requirements on scoping will drive clarity in the thinking of organizations in scoping the management system. Certiication bodies will, as before, look at how organizations has deined its scope, ensuring that this is both appropriate and is relected accurately by the management system and also in the scope of any certiicate issued. 4.4 Quality management system and its processes This clause basically states that the organization needs to establish, implement, maintain and continually improve a management system in order to deliver the required products, services and performance required under the scope. This should also be familiar to organizations which implement management systems in order to deliver compliance and improvement. Where this clause is more focused is in requiring organizations to understand more about the range of processes relevant to the scope of the management system. The term process is deined as; “a set of interrelated or interacting activities which transforms inputs into outputs”. For those who are committed to a management system which is at the core of their business, this will probably already be an integral part of that system, although you might need to review how effectively you connect those processes and understand the inluence and impact of those processes on each other and on the business. This should also elevate the system in terms of its importance and value to the business, because it should drive more meaningful analysis of the key business processes and critical aspects of those processes. In practical terms it will require an organization to more fully analyse its processes and ensure that there is good understanding of how they interact with each other- and not operate as isolated procedures without overlap. Clause 4 introduces some signiicant innovations to the management system world, and could represent a challenge to some organizations who have not viewed the management system as pivotal to the business, focussed as it is on raising management systems to a higher level and to be more central to the way an organization functions. 5. Leadership This clause includes a good proportion of content which will be familiar from ISO 9001:2008 but also introduces some signiicant changes on overall leadership and commitment and the expectations for top management to engage more fully with the critical aspects of the quality management system. 5.1 Leadership and commitment This clause encompasses a range of key activities which top management need in order to “demonstrate leadership and commitment with respect to the management system”. Therein lies one of the innovations delivered by the common HLS – top management must show leadership of the management system rather than just demonstrate commitment to it. The standard is driving the oversight of the management system to the highest level of management and making it a key component of the organization and its core business processes and activities. It doesn’t mean that senior management have to be able to regurgitate the policy or recite the objectives and targets – what it means is that an internal or external interested party should feel entitled to have a discussion with leadership about

core and critical aspects of the business, because these are at the heart of the management system. A further aim of this requirement is to fully determine market/customer needs and expectations. This information then acts as an input into determining strategy, which in turn provides direction and facilitates development of a management system capable of satisfying the targeted market or customer. This is an ongoing process, which can be achieved by many different means. Whilst not speciied in the standard, documented information could include market surveys, customer meeting minutes, questionnaires and other areas of research. Customer focus has remained very similar in context to ISO 9001:2008, but has been extended to include determination of risk and opportunities that affect conformity of products and services. 5.2 Policy The Quality Policy is an important document because it acts as the driver for the organization. It provides the direction and formally establishes goals and commitment. Top management should ensure the policy is appropriate and compatible with strategic direction. The policy needs to be communicated to all employees and they need to understand the part they have in its deployment. ISO 9001:2015 adds requirements for the policy to be documented and, as appropriate, be available to interested parties. 5.3 Organizational roles, responsibilities and authorities For a system to function effectively, those involved need to be fully aware of what their role is. Top management must ensure that key responsibilities and authorities are clearly deined and that everybody involved understands their role. Deining roles is a function of planning, ensuring awareness can then be achieved through communication and training. It is common for organizations to use job descriptions or procedures to deine responsibilities and authorities. In ISO 9001:2015, top management are more directly identiied as being responsible for ensuring that these aspects of the system are properly assigned, communicated and understood. The speciic role of a Management Representative has been removed – the standard still contains all of the key activities and responsibilities of that previously identiied role, but these now lie more directly within the core structure of the organization - including top management. Clause 5 contains much familiar content, but with greater emphasis on leadership and commitment and the expectation that top management will be more actively engaged with the management system. Page 7 DNV GL AS, NO-1322 Høvik, Norway, Tel: +47 67 57 99 00, www.dnvgl.com Version 24.09.15 6. Planning This clause is an excellent addition to ISO 9001:2015, introducing the concept of risk (and opportunity) via the HLS. DNV GL has been in the “risk” business for a very long time. As well as working with our customers to help manage risk, we have been delivering Risk Based Certiication since 2004. This innovative approach is based on an audit being built around relevant areas of risk to the organization, auditing in depth to assess whether the organization is managing that risk effectively. 6.1 Actions to address risks and opportunities In basic terms, this clause requires the organization to; n Understand the range of risks and opportunities relevant to the scope of the organization and determine actions, objectives and plans to address them n In understanding those risk and opportunities, use the inputs that the organization has identiied in understanding its context as required in clause 4.1, and the views and inputs from interested parties in clause 4.2 The strength of this clause lies in

both introducing the principles of risk and opportunity to management systems standards via the HLS, and by connecting it very clearly to the processes deined under clause 4 (the clause for determining the context of the organization and also considering the views and inputs from interested parties). A well-established approach already implemented by many organizations is the use of risk registers, which if properly managed and implemented can effectively manage risks and opportunities across a wide range of areas and issues. There will also be other approaches which result from the various relevant clauses of 9001 (e.g. the results from clause 4.1 and 4.2) along with management of change, with an overall analysis and review resulting in objectives, targets and plans. The depth and complexity of approach will depend signiicantly on the size and complexity of the organization, as well as other factors which could include the level of external regulation, existing requirements for public reporting, shareholder interests, public proile, numbers and types of customers, range and types of suppliers. Hence there will be a range of approaches which will be appropriate for the wide spectrum of organizations. It is worth reviewing the introductory clause 0.3.3 and Annex A.4 of the standard, which discusses the overall concept of “risk-based thinking”, which covers the need for an organization to consider all aspects of risk, and the fact that the revisions to 9001 bring the concept of risk to the fore as a generic and fundamental term. 6.2 Quality objectives and planning to achieve them As part of the planning process, top management needs to set quality objectives which will help to turn the Quality Policy into reality. Objectives should be consistent with the Quality Policy and be capable of being measured. This clause requires the organization to establish quality objectives and plans, ensuring that these are clear, measurable, monitored, communicated, updated and resourced. There are many different types of objectives that could be considered; market position and/or growth, process effectiveness and/or eficiency, improved awareness levels, maintenance of present position, reduction in quality costs, improvements in product conformity/reduction in defect rates, improved customer satisfaction etc. The objectives need to be deployed throughout relevant parts of the organization and must be meaningful to those who are assigned responsibility for achieving them and those whose activities contribute to their achievement. Documented information needs to kept in relation to objectives and there will need to be evidence regarding monitoring of achievement. 6.3 Planning of changes This clause sets requirements to ensure that needed changes to the management system is carried out in a planned manner. This include to consider potential consequences of change, availability of resources and deining roles and responsibilities. Changes to the management system can be needed in case of acquisition of companies, introduction of new products and services etc. Page 8 DNV GL AS, NO-1322 Høvik, Norway, Tel: +47 67 57 99 00, www.dnvgl.com Version 24.09.15 7. Support An effective quality management system cannot be maintained or improved without adequate resources. As a function of planning, such resources should be determined and provided. This includes contract or project speciic resources. This clause gathers together in one place all the areas relating to the “people, place and procedural” aspects of the management systems. The basic HLS clauses cover the following; n 7.1 Resources n 7.2 Competence n 7.3 Awareness n

7.4 Communication n 7.5 Documented Information 7.1 Resources The main intention behind this general requirement is that the people working within the quality management system are competent to fulil their duties, supported by equipment and infrastructure that is it for purpose. There must be adequate provision of infrastructure such as buildings, equipment, IT systems, transport, etc. Determining what is needed and what maintenance programme should be developed to ensure its continuing capability is part of planning. The work environment of an organization has many human and physical factors that can inluence quality, effectiveness and eficiency. These factors need to be identiied and managed and can include; protective equipment, ergonomics, heat, noise, light, hygiene, humidity, vibration, temperature etc. The relevant factors are obviously different for each product or service.An example of a work environment issue could be control of humidity in a paint shop. There are no speciic documentary requirements required by ISO 9001:2015, but work environment criteria are often found in procedures, contracts, speciications and codes of practice. Evidence of compliance should be available via retained documented information. The organization must determine what monitoring and measuring has to be undertaken and provide evidence that it was undertaken using correct and reliable equipment. Regular calibration and maintenance (and retained documented information) is one way to provide conidence that results are reliable. Critical measuring equipment must be available and in a known state of accuracy to provide assurance and evidence that products meet their relevant requirements. This also includes software. For ISO 9001:2015, these familiar requirements relating to the provision of resources for the management system and the effective delivery of the scope of services are refreshed to relect the fact that these assets can now be broader and can cover not just equipment and hardware. There is also a very interesting additional requirement termed “organizational knowledge”, which relates to ensuring that the organization understands internal and external knowledge needs and can demonstrate how this is managed. This could also include knowledge management of resources, and ensuring that there is effective succession planning for personnel, and processes for capturing individual and group knowledge. 7.2 Competence In order to determine competence, competence criteria need to be established for each function affecting quality. This can then be used to assess existing competence and determine future needs. Where criteria are not met, some action is required to ill the gap. Training or reassignment may even be necessary. Retained documented information is required to be able to demonstrate competence. Recruitment and induction programmes, training plans, skills tests and staff appraisals often provide evidence of competence and their assessment. Competency requirements are often included in recruitment notices and job descriptions. 7.3 Awareness Personnel need to be made aware of the relevance of their activities and how they contribute to achievement of the quality objectives and the effectiveness of the management system and resulting organizational performance. Induction programmes and staff reviews are often used for this purpose. 7.4 Communication ISO 9001:2015 brings (through the HLS) a clear emphasis on the importance of both internal and external

communications (i.e. greater emphasis on external communication than the 2008 standard). The clause emphasizes the need to plan and implement a process for communications along the familiar ‘who, what, when, how’ principles. Effective communication is essential for a management system. Top management need to ensure that mechanisms are in place to facilitate this. It should be recognised that communication is two-way and will not only need to cover what is required, but also what was achieved. In other words, what was planned and what was achieved? Changes in the quality management system should be communicated appropriately to interested parties (albeit in practice this is mainly internal parties) and should identify appropriate levels of re-training. Mechanisms for communication could include; meetings, notice boards, in-house publications, awareness raising seminars, toolbox talks, intranet, email, etc. 7.5 Documented information Most of the ISO 9001:2015 text is familiar, being similar to the requirements of ISO 9001:2008, but there is some logical broadening to encompass electronic and webbased environments. It is worth emphasising here that the standard no longer mandates the need for documented procedures – it is up to the organization to decide what is needed. However, it does specify on a number of occasions the need to maintain or retain documented information, in order to give structure, clarity and evidence of the system being maintained and effective. The term “documented information” now replaces the previously used terms “documented procedure” and “records”. Documented information can be in any format as long as it provide appropriate evidence to demonstrate compliance, and such documented information does not mean there has to be a procedure for everything – in fact, it can be in any format decided by the organization. With ISO 9001:2015, there is more additional text and a number of sub-sub-clauses, but these are mainly driven by the need to ensure that content from the existing ISO 9001:2008 is carried over into the appropriate and suitable clause of ISO 9001:2015. In most areas this clause does not require any signiicant changes, but there are some of the additional requirements which will require some new thinking, particularly around organizational knowledge. The changes introduced with the HLS in terms of not speciically requiring documented procedures is in reality not a signiicant issue – organizations still need to look at where documented information (e.g. processes, procedures, data, records) is critical for the management systems and its effective operation. 8. Operation This clause basically represents the production and operational control parts of the standard – the ‘engine house’ of production. There are a signiicant number of clauses added to the basic HLS. 8.1 Operational planning and control This clause makes very clear statements about the importance of linking to the critical elements of clause 4.4 where the critical processes and their interactions are determined, and to actions determined in ch. 6. There are also some additional requirements on control of changes, which are made more explicit now, and also on control over outsourced processes (previously covered under the purchasing clause of ISO 9001:2008). 8.2 Requirements for products and services There must be a process to ensure that the needs and expectations of customers (and their requirements) are determined. This should include the determination

of the intended product use and any statutory requirements that apply to the product in its intended market. Only once all requirements are identiied can they be reviewed. Once determined, requirements need to be reviewed by the organization prior to any commitment to supply to ensure that they are understood, that any anomalies are resolved and that the organization has the ability to meet the requirements. There are numerous incidents of offers being made and orders accepted without fully understanding whether the business can meet the contract and has the capability to deliver. Examples of input documentation could be; enquiries, contract speciications and clariications, whilst examples of output documents could be offers, tenders or contractor's proposals. Communication needs to be planned to ensure that all necessary information is available when needed, from both external and internal sources. This could also include feedback from the customer, which is further discussed under the heading of customer satisfaction (clause 9.1.2). Documented information pertaining to communication are not speciied, but typically they can include contracts, speciications, drawings, e-mails, letters, transmittals, meeting minutes, complaints etc. ISO 9001:2015 adds content on communications relating to customer property along with contingency actions. 8.3 Design and development of products and services There must be a systematic approach to controlling design activities and product development. This will involve design planning, which should include stages of design, review, veriication and validation activities. Although not required by ISO 9001:2015, a common document produced is a design plan, which outlines how the design will be managed throughout the design process. Design and development inputs can include customer speciications, statutory requirements, information from previous designs, budgetary considerations etc. Each organization should decide how the design is developed but the output needs to be veriied against the design input requirements. Therefore, the output needs to be in a format that will enable veriication. Typical outputs include drawings, speciications, instructions, schedules, user manuals etc. Review of the design should be undertaken at planned stages to ensure that the design is satisfactory and to trigger solutions to any problems encountered. Documented information pertaining to design reviews and necessary actions needs to be retained. Typically these could include meeting minutes, altered drawings, sketches, approval documents etc. Veriication is basically a process whereby the design is checked to ensure that what has been designed meets the input requirements. For example, checking design calculations to ensure that an air conditioning unit has the desired capacity. The results and any actions required as a result of the veriication process must be retained as documented information. Typically these could include alternative calculations, approvals, comparison reports etc. Validation needs to be performed to ensure that the product can meet the basis of its design. For example, testing a prototype air conditioning unit to ensure it can hold the desired temperature under the deined operating conditions before mass production commences. Validation should, where possible, be completed prior to delivery. Results of the validation process and any actions need to be retained as documented information. Typically these could include test results, prototype feedback, user testing etc. Changes to design requirements can come at any time

and as a result of many factors. They can also signiicantly impact on the design in progress. Any resulting changes in design must be reviewed, veriied and validated where Page 11 DNV GL AS, NO-1322 Høvik, Norway, Tel: +47 67 57 99 00, www.dnvgl.com Version 24.09.15 necessary. Design changes need to be identiied and retained as documented information. This clause follows much of the ISO 9001:2008 clause 7.3, but with clearer structure and requirements for design and development planning, consideration of needs of customers and from key documented information (clause 8.3.2); for design and development inputs, a wider set of inputs including resource considerations and potential consequences of failures (clause 8.3.3). Clear requirements for retention of documented (design) information are stated. 8.4 Control of externally provided processes, products and services The main aim of this requirement is to ensure that the purchased processes, products or services you require (e.g. components for your product) will ensure that you can meet your customer's requirements. As a irst step it is necessary to have conidence in the entity supplying the process, product or service. Some form of initial evaluation process should be in place, but this should be lexible as not all suppliers have the same impact on the inal product/service. The criteria for selection, evaluation and re-evaluation of suppliers must be determined and applied. Controls could then be put in place based on the results of the evaluation and the relative impacts they could have (risk management) must be determined and applied. A second step to ensuring that purchased process, product or service meets requirements is to provide all necessary information to the supplier. They should not have to second-guess what is needed, and clarity is essential, not just in terms of product speciication but also in terms of operator qualiication, quality control, quality assurance, documentation, delivery times etc. The purchase requirements should also be checked for adequacy before they are communicated to your supplier. Typical documented information could include supplier quotations, purchase orders, contracts and associated review records. A third step is the veriication of the process, product or service that you have procured. This could be done by various means at the pre-shipment stage or upon receipt. For example, receiving inspection or test records, or through verifying a certiicate of product conformity. Some organizations undertake audits of their key suppliers or witness factory acceptance tests. Activities could also involve your customer conducting a joint veriication with you at their premises. As a fourth step, suppliers need to be re- evaluated periodically (or continually) against predetermined criteria. The results of supplier evaluation and reevaluation need to be maintained, and could be in the form of references, trial orders, product speciications, audit results, performance data, defect rates etc. Although not a requirement of the standard, some organizations choose to compile an approved supplier list for ease of reference. ISO 9001:2015 covers much broader ground than ISO 9001:2008 in terms of referring to externally provided processes, products or services rather than the existing clause on purchasing. It also makes clear the criteria for applying the requirements. 8.5 Production and service provision This requirement is aiming to ensure that your production activities and operations are planned and then conducted in a manner ensuring control. This can also include operations at the customers' premises, such as installation. There are many different

ways to achieve control and methods can include controlled processes, procedures, drawings, speciications, work instructions, quality plans, operating and process criteria. This requirement applies to products that cannot be truly veriied until they are in use (e.g. a match – as the only effective way to test whether a match will work is to strike it!). A business must have conidence in the ability of its process to consistently deliver and meet customer expectations. Processes may also need re-validation from time to time because conditions, people and materials can change. Retained documented information relevant to process validation is required and may consist of records of operator qualiications, materials used, equipment used, methods used, the work environment etc. Page 12 DNV GL AS, NO1322 Høvik, Norway, Tel: +47 67 57 99 00, www.dnvgl.com Version 24.09.15 In almost all organizations there is a need to formally identify product or service and determine its status or level of readiness at any given point in time. There may also be the need to trace a product or service (e.g. for legal requirements). The main aim is to be able to prevent incorrect use of suitable products or prevent or limit the use of unsuitable products. In some industries traceability is a requirement throughout processing and beyond to assist in the event of recall. In such cases unique identiication of the product needs to be controlled and recorded. There are many different ways to identify and trace products/ services such as; batch numbers, production dates, inspection reports, colour coded labels, designated storage locations, packaging bar codes, service reports, job numbers, project/ report numbers, part numbers, coniguration information etc. Some organizations use products or intellectual property (e.g. patents) provided by customers. If so, then it is necessary to ensure that what has been provided is suitable for the intended application and thereafter is used properly and protected against loss or damage. To support this, there could be records of receipt, inspection, use, loss, damage or return (again there are clear requirements stated for retention of documented information). Product need to be preserved - from raw materials during receipt, storage and processing to inished product up to the point of delivery. The aim is to ensure continued suitability for use. In the service industry this could also include the preservation of data or reports on electronic media. When planning preservation of products, there should be consideration of the needs of customers, regulators as well as identiication, handling, packaging, storage and protection requirements. The type of product will naturally dictate the infrastructure and controls necessary. Frozen food, for example, will require cold storage and be governed by regulation, whereas other products may just need protection from direct sunlight. Documentation may include storage procedures and criteria, records of receipt and issue, records to demonstrate legal compliance, expiry dates, damaged or lost goods, returns etc. ISO 9001:2015 brings much that is similar in content and intent to the existing requirements in ISO 9001:2008. The main change is with the two additional clauses – “8.5.5 Post-delivery activities” and “8.5.6 Control of changes” – now much more clearly deined and speciied. 8.6 Release of products and services The organization must monitor and measure the characteristics of the product to verify that product requirements have been met and evidence of conformity with the acceptance criteria must be maintained. Retained documented information must indicate

the person(s) authorising the release of product for delivery to the customer. 8.7 Control of nonconforming outputs This requirement is intended to ensure that nonconforming product is prevented from further processing, use or delivery. Once identiied, and regardless of when identiied (e.g. during processing or after delivery) any nonconforming product should trigger a process whereby an authorised and competent person should decide what course of action is to be taken. Options can include scrapping, supplying under concession, alternative uses, product rework or recall. ISO 9001:2015 has broadened the terminology and scope of the operations and production clause, whilst retaining much of the ISO 9001:2008 content. The approach adopted is also aligned with the common process-based aspects of the HLS, and covers more effectively the complete end-to-end production and service provision process. Page 13 DNV GL AS, NO-1322 Høvik, Norway, Tel: +47 67 57 99 00, www.dnvgl.com Version 24.09.15 9. Performance evaluation 9.1 Monitoring, measurement, analysis and evaluation Collection and analysis of relevant data is necessary to measure the suitability and effectiveness of the management system and to identify opportunities for improvement. Business goals and objectives should considered when deciding what to analyse and comment. Methods of analysis vary greatly in terms of applicability and complexity. Simple bar charts are suficient for some activities whereas Statistical Process Controls are necessary for others. The methods selected should only be as complex as needed. As a minimum, analysis should be performed in relation to customers, product conformance, processes and supplier performance. Customer feedback is one very good indicator of management system and business performance. There are many ways to capture feedback and businesses should think wider than just using questionnaires or complaints. For example, other methods include interviews, customer meetings and market surveys. The aim is to monitor information that will help understand customer perception of the product/ service and to facilitate analysis to improve satisfaction. This clause contains familiar content on customer satisfaction and analysis and evaluation, with requirements broadly similar to ISO 9001:2008, but with a more holistic approach and a stronger drive for evidence of analysis and evaluation of key performance data as the basis of fact-based decision making. 9.2 Internal audit Internal audits have always been a key element of ISO 9001 in helping to assess the effectiveness of the quality management system. An audit programme needs to be established to ensure that all processes are audited at the required frequency, the focus being on those most critical to the business. To ensure that internal audits are consistent and thorough, a clear objective and scope should be deined for each audit. This will also assist with auditor selection to ensure objectivity and impartiality. To get the best results, auditors should have a working knowledge of what is to be audited, but management must act on audit results. This is often limited to corrective action relating to any nonconformities that are found, but other indings can also be used to trigger prevention and improvement. Follow up activities should be performed to ensure that the action taken as a result of an audit is effective. This clause is largely the same as in ISO 9001:2008. Page 14 DNV GL AS, NO-1322 Høvik, Norway, Tel: +47 67 57 99 00, www.dnvgl.com Version 24.09.15 9.3 Management review The main aim of management review is to ensure the continuing

suitability, adequacy and effectiveness of the quality management system, and its alignment with the strategic direction of the organization. Only through conducting the review at suficient intervals (remember, management review does not have to be just one meeting, held once per year), providing adequate information and ensuring the right people are involved can this aim be achieved. The standard details the minimum inputs to the review process. Top management should also use the review as an opportunity to identify improvements that can be made and/ or any changes required, including the resources needed. The input to management review should include information on; (a) the status of actions from previous management reviews; (b) changes in external and internal issues that are relevant to the quality management system (c) information on the performance and effectiveness of the quality management system (d) Adequacy of resources (e) the effectiveness of actions taken to address risks and opportunities (f) Opportunities for improvement The output from the management review shall include decisions and actions related to opportunities for improvement, need for changes to the quality management system and resource needs. Documented information pertaining to the management review is required to be retained. This will usually be in the form of meeting minutes, but could also be in the form of a report, notated with required actions after its review (as the management review process does not necessarily have to be a meeting). This clause is largely the same as ISO 9001:2008, but with some broader topics and alignment with the new language of risks and opportunities, and the context of the organization. 10. Improvement 10.1 General This clause provides an overview of what improvement means in the context of ISO 9001:2015 – an overall approach requiring review of processes, products and services and quality management system results, with some useful reminders that the mechanisms for such improvements can be achieved by a variety of means; correction, corrective action, continual improvement, breakthrough change, innovation and reorganization. 10.2 Nonconformity and corrective action The main aim of the corrective action process is to eliminate the causes of actual problems so as to avoid recurrence of those problems. It is a reactive process, in that it is triggered after an undesired event (e.g. discovery of nonconforming product). In essence, the process uses the principles of root cause analysis. A basic approach to problem solving is “cause” and “effect”, and it is the cause that needs to be eliminated. Action taken should be appropriate to the impact of the problem (risk). As part of the corrective action process, the effectiveness of action taken must be checked to ensure it is effective. It is worth noting that corrective action alone will not bring about improvement in the quality management system. It merely brings the control level back to where it should have been before the nonconformity occurred. Additionally, although not an explicit requirement of the standard, corrective actions should also take into consideration any speciic training and communications needs. For the clause on nonconformity and corrective action, much of the content is familiar and similar to ISO 9001:2008 but the term “preventive action” has now been deleted from the requirements section of the standard (but gets a mention elsewhere in the context of risk-based thinking), the new HLS being built on the fundamental principles of risk management, which embodies

the need to identify risk and manage those risks, with the ultimate goal of risk elimination. Page 15 DNV GL AS, NO-1322 Høvik, Norway, Tel: +47 67 57 99 00, www.dnvgl.com Version 24.09.15 10.3 Continual improvement One of the aims of any organization should be to improve and this is a key tenet of ISO 9001. There are many ways to identify and drive improvement. All measurement results can be analysed to determine where improvement is required or desired. Policy and objectives can then be set and deployed through prevention and improvement programmes. Improvement does not have to take place in all areas of the business at the same time. Focus should be relevant to risks and beneits. Improvement can be incremental (small changes) or breakthrough (new technology). In reality both methods will be used at some point in time. The content of this clause on continual improvement is similar to ISO 9001:2008 and effectively re-emphasises elements of performance and improvement documented elsewhere in the standard. ABOUT DNV GL - BUSINESS ASSURANCE Driven by our purpose of safeguarding life, property and the environment, DNV GL enables organizations to advance the safety and sustainability of their business. DNV GL is a leading provider of classification, certification, verification and training services. With our origins stretching back to 1864, our reach today is global. Operating in more than 100 countries, our 16,000 professionals are dedicated to helping our customers make the world safer, smarter and greener. As a world- leading certification body, DNV GL helps businesses assure the performance of their organizations, products, people, facilities and supply chains through certification, verification, assessment, and training services. We also deliver deep insight and pragmatic support to major companies enabling them to build effective sustainability strategies. Partnering with our customers, we build sustainable business performance and create stakeholder trust.

"Quality Assurance of Pharmaceuticals: a Compendium of Guidelines and Related Materials," Volume 2, published by the World Health Organization (WHO) in 2023. This volume focuses on

Good Manufacturing Practices (GMP) and inspection, serving as a resource for manufacturers, regulators, and other stakeholders to ensure the quality, safety, and efficacy of medical products.

Key information about this document includes:

Content and Organization

- The compendium contains a total of

45 guidelines related to GMP and pharmaceutical inspection.

- It is organized into six main sections: GMP main principles, starting materials, specific medical products, related guidelines, laboratory guidelines, and inspections.
- **Volume 1**, first published in 1997, covers regulatory systems, product development, registration, quality control, distribution, and related standards.

- **Volume 2**, first published in 1999, concentrates on GMP and the inspection of manufacturers and distribution channels.

Updates in the Tenth Edition

The tenth edition includes several updates to keep the recommendations current and relevant.

- **Eight new guidelines** were introduced, covering areas that were previously unexplored. These include:
    - GMP for investigational radiopharmaceuticals and medicinal gases.
    - Recommendations on environmental aspects for the prevention of antimicrobial resistance.
    - Health-based exposure limits (HBELs) in cleaning validation.
    - Good practices for research and development facilities.
- **Ten guidelines were revised** to reflect the latest advancements and address new challenges in the pharmaceutical industry. The revised guidelines include those for:
    - GMP for sterile pharmaceutical products.
    - Water for pharmaceutical use.
    - Radiopharmaceuticals and investigational products.
    - Data integrity.
    - Technology transfer in pharmaceutical manufacturing.
    - Good storage and distribution practices for medical products.

Core Principles of GMP

The document emphasizes that GMP is a crucial part of quality management, ensuring products are consistently produced and controlled according to quality standards. Key principles include:

- Senior management is responsible for implementing and maintaining an effective

Pharmaceutical Quality System (PQS).

- The PQS should ensure that products are designed and developed with GMP in mind, production and control operations are clearly defined, and all necessary controls and validations are performed.
- **Quality risk management (QRM)** is a systematic process for assessing, controlling, communicating, and reviewing risks to product quality.

- All manufacturing processes should be clearly defined and validated to consistently produce products of the required quality.
- Documentation and records must be accurate, legible, and retained for a specified period to ensure traceability.

Specific Guidelines

The compendium provides detailed guidance on a wide range of specific practices and product types:

- **Starting Materials:** GMP is outlined for active pharmaceutical ingredients (APIs) and pharmaceutical excipients, including procedures for purchasing, sampling, storage, and handling.
- **Sterile Products:** This section, revised in 2022, provides guidance on minimizing risks of microbial and particulate contamination during the manufacture of sterile products. It details requirements for cleanrooms (Grades A, B, C, and D), personnel qualifications, sterilization methods (e.g., heat, radiation), and aseptic processing.
- **Investigational Products:** The 2022 revised guideline on GMP for investigational products outlines requirements for products used in clinical trials, emphasizing the need for a quality management system that adapts to the product's development stage.
- **Radiopharmaceuticals:** The guide includes a new guideline for investigational radiopharmaceuticals and a revised one for radiopharmaceutical products, developed in collaboration with the International Atomic Energy Agency (IAEA). It addresses the unique challenges of manufacturing these products, such as small batch sizes and short shelf-lives.
- **Herbal Medicines:** A dedicated guideline provides supplementary GMP for herbal medicines, which are complex due to the variability of plant-based materials. It covers specific processing techniques like drying, extraction, and fermentation.
- **Inspections:** The compendium offers guidance on conducting inspections, including pre-approval inspections, and provides a model report format. It also includes guidance on desk assessments as a way to verify compliance without a physical on-site inspection.

This document is intended to be a centralized, continuously updated resource to help regulators and manufacturers uphold international standards for pharmaceutical quality assurance.

- Query successful

A quality assurance (QA) plan is a comprehensive guide for pharmaceutical companies to meet regulatory requirements, establish continual improvement systems, and create a quality-driven culture. It's a broad concept that involves reviewing all aspects that can impact patient outcomes, including the development process, raw materials, manufacturing, packaging, transportation, and storage. Without a solid QA plan, a company can't demonstrate compliance or ensure its products meet quality and safety standards.

The QA plan is generally the responsibility of the QA department, but an effective plan will influence every part of the organization. Key components of a comprehensive quality plan include:

- **Document Control** All FDA-regulated and ISO-certified companies must have a system for managing and controlling documents. This system should address the entire document lifecycle, from drafting to release and archival, and support the use of audit trails.
- **Training** The plan should include training for new hires, current staff, and contractors, with a curriculum based on standard operating procedures (SOPs). Ongoing employee monitoring and key performance indicators (KPIs) for assessments should also be addressed to foster a culture of continuous improvement.
- **Deviation** Companies are required to document any deviation from SOPs or other requirements. The plan should detail the process for identifying, recording, investigating, and proposing corrective actions for these deviations.
- **Laboratory OOS (Out-of-Specification)** The plan must outline how to investigate the root causes of laboratory results that don't align with expectations.
- **CAPA (Corrective and Preventive Action)** A CAPA system helps companies resolve quality issues, reduce complaints, and maintain regulatory compliance. The plan should cover each stage of CAPA, including identification, evaluation, investigation, and resolution.
- **Internal Audits** These are an important tool for compliance and identifying issues before they lead to quality problems. The plan should define audits as a tool for continuous process improvement and employee training.
- **Management Review** This system ensures that leadership is involved in the quality management process. It's a requirement of ISO 9001 and should involve regular meetings to discuss improvements to quality systems, processes, and products.

A quality management system (QMS) plays an integral role in implementing a QA plan. A QMS is a formalized system that documents processes and procedures for achieving quality objectives. For most small to mid-sized pharmaceutical companies, a cloud-based, scalable QMS is the best choice because it offers efficiency, ease of use, and global accessibility.

When selecting a QMS, key factors to consider are simplicity, ease of use, and scalability. The software should simplify compliance and align with regulatory requirements.

Shifting from a compliance-driven culture to a quality-driven one can bring significant value to a company. When quality is seen as a profit-driving force, executives are more likely to invest in the necessary changes and resources for employee training and engagement. A strong QA plan combined with the right QMS platform can prevent waste, help with timely drug registration, and offer major operational benefits.