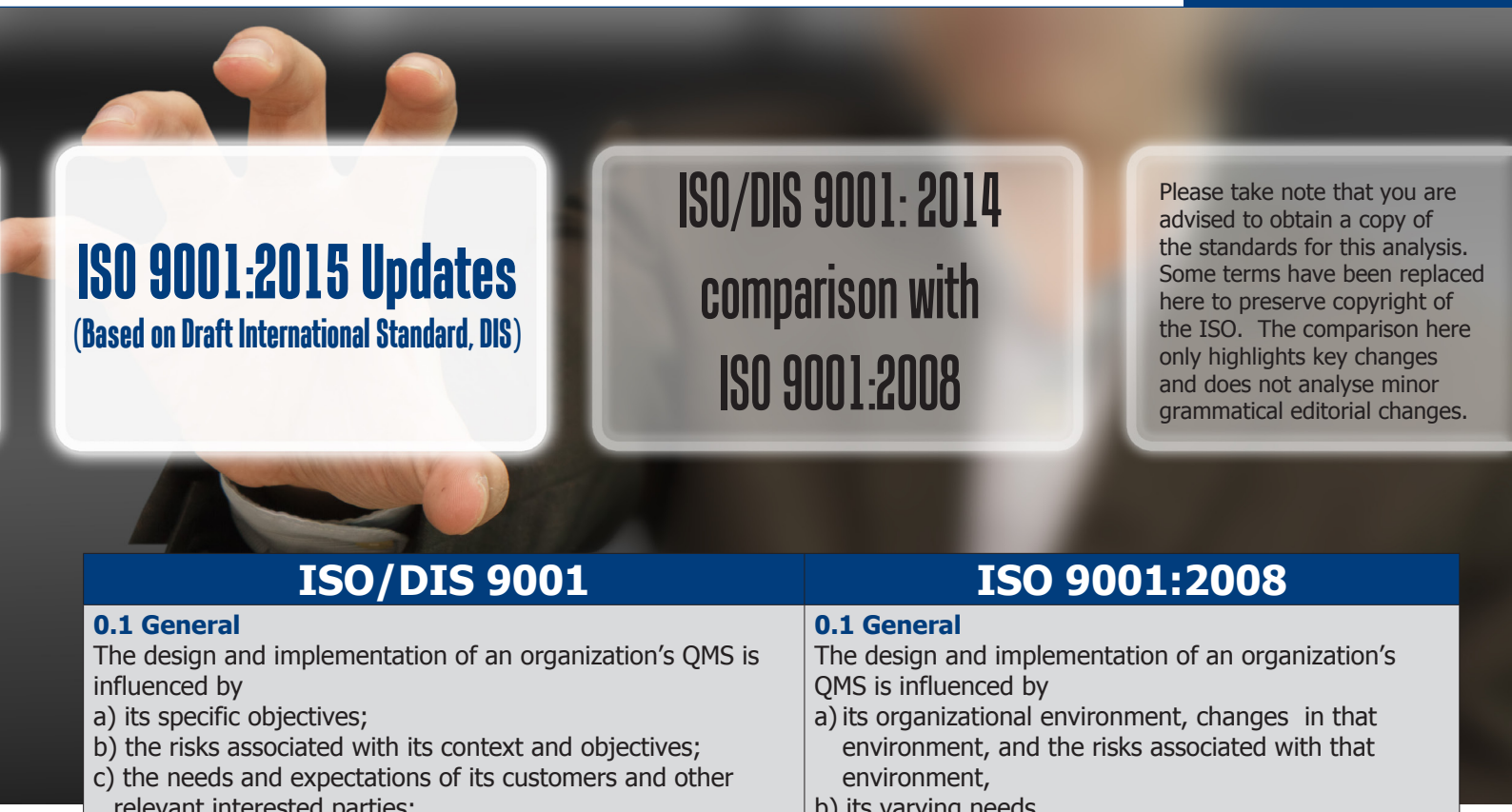

ISO 9001:2015 Updates
(Based on Draft International Standard, DIS)

ISO/DIS 9001: 2014 comparison with ISO 9001:2008

Please take note that you are advised to obtain a copy of the standards for this analysis. Some terms have been replaced here to preserve copyright of the ISO. The comparison here only highlights key changes and does not analyse minor grammatical editorial changes.

ISO/DIS 9001	ISO 9001:2008
0.1 General The design and implementation of an organization's QMS is influenced by a) its specific objectives; b) the risks associated with its context and objectives; c) the needs and expectations of its customers and other relevant interested parties; d) the products and services it provides; e) the complexity of processes it employs and their interactions; f) the competence of persons within or working on behalf of the organization; g) its size and organizational structure. There are two new items to consider (c) and (f). Instead of the term organizational environment in version 2008, the DIS states "context" which includes internal factors such as organizational culture, and external factors such as the socio-economic conditions under which it operates.	**0.1 General** The design and implementation of an organization's QMS is influenced by a) its organizational environment, changes in that environment, and the risks associated with that environment, b) its varying needs, c) its particular objectives, d) the products it provides, e) the processes it employs, h) its size and organizational structure.
0.2 The ISO standards for quality management This clause has been rewritten to state the three core standards of ISO 9000, 9001 and 9004. It also introduces the quality related ISO 10000 range which are listed in Annex C. These ISO 10000 standards can provide assistance to the organization when establishing or seeking to improve their system, process or their activities.	**0.3 Relationship with ISO 9004**
0.3 Process approach A new model has been introduced which reference the clause numbers in the DIS.	**0.2 Process approach**
0.4 Plan-Do-Check-Act cycle This was once located in the same clause as "process approach" but now moved to a new sub-clause. An illustration is included to show application of PDCA within a process.	**0.2 Process approach**

ISO/DIS 9001	ISO 9001:2008
0.5 Risk-based thinking In version 2008, the standard user was introduced to the concept of risk associated with the organizational environment however there is no clausal requirements to evidence this. In this new standard, risk plays a more prominent role with explicit requirements to determine risks and take actions.	**0.1. General**
0.6 Compatibility with other management system standards ISO adopts the high level structure of Annex SL (specified in the procedures specific to ISO) in management system standards which will result in improve alignment between these standards.	**0.3 Compatibility with other management systems**
1 Scope Unchanged from version 2008 but there is no further division into subclauses. The subclause 1.2 Application in the 2008 version which included exclusion to the scope has been rearranged into clause 4.3 (see further down). In the DIS, the term exclusion is not used.	**1 Scope** **1.1. General**
2 Normative reference No normative reference stated. Version 2008 stated ISO 9000 standard as reference. Reason for this is the terms and definitions previously in ISO 9000 have been incorporated in clause 3 below.	**2 Normative reference**
3 Terms and definitions The version 2008 made reference to ISO 9000 but the DIS included the relevant terms. As a result, the users of the new ISO 9001 need not obtain the ISO 9000 for reference. There are some new terms defined in the DIS previously not in the ISO 9000, such as monitoring, performance, risk, outsource and involvement.	**3 Terms and definitions**
4 Context of the organization New clause title	**Nil**
4.1 Understanding the organization and its context This is a new requirement whereby an organization need to determine external and internal issues that may affect the performance of its system. Most organizations do conduct this analysis at management level but now they may have to show evidence of this to auditors.	**Nil**
4.2. Understanding the needs and expectations of interested parties This is a new requirement. Organizations need to determine the requirements of customers, shareholders, employees, suppliers, society, etc which are relevant to its quality management system. This will add more value to the quality management system because often the customer requirements are not the only ones that affect how the system operates.	**Nil**

ISO/DIS 9001	ISO 9001:2008
4.3. Determining the scope of the quality management system Scope determination is made clearer with consideration of a) external and internal issues (in 4.1 above) b) requirements of interested parties (in 4.2 above) c) products and services offered The term "exclusion" is omitted. Instead the standard states "requirements that cannot be applied". As per previous standard, an organization has to provide justification for non-application. In short, organizations may have to re-look at those requirements previously excluded from the scope of the system just because they choose not to include although those requirements were applicable. The new standard states that where a requirement within the determined scope can be applied, then it shall be applied. Definition 3.04 Management System included a note to explain that the scope may include the whole organization, specific functions, specific sections or one or more functions across a group of organizations. Scope is required to be documented, but not necessary in a quality manual because the new standard does not prescribe a manual.	**1.2 Application**
4.4. Quality management system and its processes There is less emphasis on "documenting" the system and more on process approach, including the need to determine the following additional process characteristics: - process input and outputs - performance indicators - responsibilities and authorities - risks, opportunities and actions to address them Documented information is required both to manage the process and to provide evidence but there is no requirement to describe the process interaction in a quality manual.	**4.1. General requirements**
5. Leadership	**5 Management Responsibility**
5.1. Leadership and commitment	**5.1. Management Commitment**
5.1.1. Leadership and commitment for the quality management system Additional commitment for top management: - accountable for the effectiveness of the system - ensuing integration of the quality management system requirements into the organization's business process - promoting awareness of process approach - ensuring that the quality management system achieves its results - engagement, direction and support to persons contributing to the effectiveness of the system - promoting continual improvement - support to other management roles	**5.1. Management Commitment**

ISO/DIS 9001	ISO 9001:2008
5.1.2. Customer focus More explicit requirements but the intent remains the same. There is however, one additional requirement: - Top management shall ensure that risks and opportunities that can affect conformity and the ability to enhance customer satisfaction are determined and addressed.	**5.2. Customer focus**
5.2. Quality Policy Additional requirement to ensure that the policy is available to relevant interested parties.	**5.3. Quality Policy**
5.3. Organizational roles, responsibilities and authorities There is no requirement for appointing a "management representative", however the responsibilities and authorities still remain. This means that the responsibilities and authorities previously held by a management representative can now be assigned to more than one person.	**5.5.1. Responsibility and authority** **5.5.2. Management representative**
6 Planning for the quality management system	**5.4.2. Quality management system planning**
6.1. Actions to address risks and opportunities This is a new requirement, perhaps the most significant addition. Version 2008 introduced the concept of risk but does not require evidence of risk being addressed within the system. The DIS requires consideration being given to risks and opportunities when establishing the system. The standard however, does not require a formal risk management or a documented risk management process. This means an organization now has to provide justification why its system is designed in a certain way, rather than just show the system being present. This provides opportunities to incorporate best practices or those practices that provide "competitive edge" to an organization rather than following set rules. With the addition of risks/opportunities determination, the requirement on "preventive action" in version 2008 has been deleted.	**Nil**
6.2. Quality objectives and planning to achieve them Although in version 2008, it is implied that the quality objectives need to be communicated, monitored and measured, the new version is explicit on these requirements. Even more explicit is the need to plan how the objectives are to be achieved, including: - what will be done, by whom and by when - resources required - how results will be evaluated.	**5.4.1. Quality Objectives** **5.4.2. Quality management system planning**

ISO/DIS 9001	ISO 9001:2008
6.3. Planning of changes This is an extension of clause 5.4.2 (b). The DIS specifies the considerations that need to be included when there are changes to the system, these include: - purpose and potential consequences - integrity of the system - availability of resources - responsibilities and authorities.	**5.4.2 (b)** ensuring integrity of the system…..when changes are planned and implemented.
7 Support New clause title	**Nil**
7.1. Resources	**6 Resource management**
7.1.1. General Consideration of resources includes those externally provided.	**6.1. Provision of resources**
7.1.2 People This clause is separated out from competence (7.2) and awareness (7.3).	**6.2. Human Resources**
7.1.3. Infrastructure The requirements are essentially the same but with minor changes to the wordings.	**6.3. Infrastructure**
7.1.4. Environment for the operation of processes Extension of the requirement i.e. now applicable for operation of its processes besides achieving conformity to product requirements.	**6.4. Work environment**
7.1.5. Monitoring and measuring resources The term equipment has been expanded to resources. Resources include instruments, people, test methods, software and also the formats for eliciting questionnaire feedback. Organizations need to determine the suitability of the resources and retain documented evidence of fitness for purpose. Where traceability is required (previously where necessary to ensure valid results), instruments (previously equipment) need to be controlled: verified/calibrated, identified and safeguarded.	**7.6. Control of monitoring and measuring equipment**
7.1.6. Organizational knowledge This is a new requirement. Organizations are required to determine, maintain and make available the necessary knowledge, in particular when there are changes. Knowledge include information such as intellectual property and lessons learned. Organizations now have to determine how the knowledge is to be captured so that it can be maintained and made available.	**Nil**

ISO/DIS 9001	ISO 9001:2008
7.2. Competence Extension of competency of those whose "work affecting conformity to product requirements" to "affect its quality performance". As per version 2008, organizations have a choice to conduct training or take other actions. A note is included to explain these actions include mentoring, reassignment, hiring or contracting out competent persons.	**6.2.2. Competence, training and awareness**
7.3. Awareness This clause is separated from competency. Explicitly stated now, awareness includes the policy, objectives, contribution and implications of not conforming with the requirements.	**6.2.2. Competence, training and awareness** **5.3. Quality policy**
7.4. Communication Previously "internal communication", now includes "external communication". More prescriptive that organizations need to determine what, when, how and with whom.	**5.5.3. Internal communication**
7.5. Documented information **7.5.1. General** **7.5.2. Creating and updating** **7.5.3. Control of documented information** There is no more distinction between "document" and "record", the new standard uses the term "documented information". It also deleted documented procedures and quality manual. That means that organizations have greater freedom on the type of document they need as long as the format is appropriate. The new requirements have been re-worded to make them applicable to any type of media especially in this age of information technology. Other than those highlighted above, there is little change on the control of documented information compared to "control of document" and "control of records".	**4.2. Documentation** **4.2.1. General** **4.2.2. Quality manual** **4.2.3. Control of documents** **4.2.4. Control of records**
8 Operation	**7 Product Realization**
8.1. Operational planning and control The term "product realization" has been replaced with "operation" so that the standard becomes more user-friendly to service industries. There are additional requirements: - to include actions to address risk/opportunity - to address control of planned changes - to review consequences of unintended changes and taking actions to mitigate adverse effects.	**7.1. Planning of product realization**

ISO/DIS 9001	ISO 9001:2008
8.2. Determination of requirements for products and services **8.2.1. Customer communication** **8.2.2. Determination of requirements related to products and services** **8.2.3. Review of requirements related to products and services** Re-arrangement of the clauses which logically starts with communication first. Two additional requirements in customer communication: - handling or treatment of customer property - specific requirements for contingency actions Review items have been extended to include two items previously listed in clause 7.2.1 - requirements not stated by the customer but necessary for specified or intended use, when known - additional statutory and regulatory requirements applicable to the products and services	**7.2. Customer-related processes** **7.2.1. Determination of requirements related to the product** **7.2.2. Review of requirements related to the product** **7.2.3. Customer communication**
8.3. Design and development of products and services **8.3.1. General** This is an additional clause to describe when "design and development" process is applicable i.e. when detailed requirements are not already established or not defined by the customer or by other interested parties, such that they are adequate for subsequent production or service provision.	**7.3. Design and development**
8.3.2. Design and development planning The whole clause has been rewritten in a listing of items that need to be considered during determination of stages and controls. There are three new items that have been included for consideration: - the nature, duration and complexity of the design and development activities - the need for involvement of customer and user groups in the design and development process - the necessary documented information to confirm that design and development requirements have been met.	**7.3.1. Design and development planning**
8.3.3. Design and development inputs Consideration of the inputs include these additional items: - standards or codes of practice that the organization has committed to implement - internal and external resources needs - potential consequences of failure due to the nature of the products and services - the level of control expected of the design and development process by customers and other relevant interested parties	**7.3.2. Design and development inputs**

ISO/DIS 9001	ISO 9001:2008
8.3.4. Design and development controls This clause combines the previous 7.3.4, 7.3.5 and 7.3.6.	**7.3.4. Design and development review** **7.3.5. Design and development verification** **7.3.6. Design and development validation**
8.3.5. Design and development outputs There is a minor expansion to the outputs: - include or reference monitoring and measuring requirements - documented information resulting from the design and development process shall be retained.	**7.3.3. Design and development outputs**
8.3.6. Design and development changes Changes to the input or output can be made during design and development process or subsequent to that. The DIS did not specify the need for verification and validation but is implied by stating "review, control and identify the changes to the extent that there is no adverse impact on conformity to requirements".	**7.3.7. Control of design and development changes**
8.4. Control of externally provided products and services The title has been changed to expand the scope to externally provided products and services which may be obtained with payment (purchased) or without payment (e.g. outsourced from other organizations within the group).	**7.4. Purchasing**
8.4.1. General The scope includes externally provided processes, products and services and controls are to be applied for the following: - products and services from external providers are incorporated into the organization's own products and services - products and services to be provided directly to the customer by the external provider on the organization's behalf - outsourced processes or part of processes. There is an additional requirement to monitor performance of external providers and maintain documented information of the results of monitoring. This is implied in the version 2008 in 8.4. analysis of data but now it is explicitly stated.	**7.4.1. Purchasing process**
8.4.2. Type and extent of control of external provision The DIS specifies that organizations need to consider the following in determining the type and extent of control: - potential impact on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements - the perceived effectiveness of the controls applied to external provider This clause shall also apply to outsourced processes within the scope of the quality management system.	**7.4.1. Purchasing process** **7.4.3. Verification of purchased product**

ISO/DIS 9001	ISO 9001:2008
8.4.3. Information for external providers The information to be communicated has been rewritten for easier understanding. Additional requirements include - the control and monitoring of the external provider's performance to be applied by the organization	**7.4.2. Purchasing information**
8.5. Production and service provision	**7.5. Production and service provision**
8.5.1. Control of production and service provision This clause is now a combination of 7.5.1 and 7.5.2 of version 2008. The words "work instructions" have been replaced with documented information allowing more freedom for organization to decide on the type of documentation it wants. There are some re-phrasing of the controlled conditions, notably: - the availability of documented information that defines the activities to be performed and the results to be achieved - the use and control of suitable infrastructure and process environment - the competence and where applicable, required qualifications of persons (previously from 7.5.2)	**7.5.1. Control of production and service provision** **7.5.2. Validation of processes for production and service provision**
8.5.2. Identification and traceability The essence of this clause is unchanged.	**7.5.3. Identification and traceability**
8.5.3. Property belonging to customers or external providers The requirements have been expanded to include properties from external providers. The controls required are essentially the same but now organizations need to address properties from supplier, outsourced parties or other external providers.	**7.5.4. Customer property**
8.5.4. Preservation Preservation, now includes transmission (e.g. of information) or transportation. The requirement to consider preservation including identification, handling, packaging, storage and protection has been moved to the note for this sub-clause. The requirement now simply states "to the extent necessary to maintain conformity to requirements".	**7.5.5. Preservation of product**

ISO/DIS 9001	ISO 9001:2008
8.5.5. Post-delivery activities This is a new clause. Previously there was just the implementation of post-delivery activities in the clause "control of production and service provision" but now there are new items to be considered to determine the extent of controlling post-delivery activities, including: - the risk associated with the products and services - the nature, use and intended lifetime of the products and services - customer feedback - statutory and regulatory requirements.	**Nil**
8.5.6. Control of changes This is a new clause. Requirements include: - review and control unplanned changes - retaining documented information on the results of the review, authorization and actions.	**Nil**
8.6. Release of products and services The essence of this clause is the same as per previous 8.2.4.	**8.2.4. Monitoring and measurement of product**
8.7. Control of nonconforming process outputs, products and services The requirement for "documented procedure" has been deleted. The actions on nonconforming products have been expanded to include: - segregation, containment, return or suspension - informing the customer - authorization for re-provision of the products and services. The requirement to record the nature of nonconformities and actions taken has been moved to sub-clause 10.2 which now requires all nonconformities to be recorded, not just those relating to nonconforming products.	**8.3. Control of nonconforming product**
9 Performance evaluation Previous clause 8 has been divided between clauses 9 and 10.	**8 Measurement, analysis and improvement**

ISO/DIS 9001	ISO 9001:2008
9.1. Monitoring, measurement, analysis and evaluation **9.1.1. General** Additional requirements include determining when to conduct monitoring and measurement and when the results shall be analysed and evaluated. Compared to version 2008, organizations now need to show that they have evaluated the quality performance and the effectiveness of the quality management system. However, the DIS no longer states "statistical techniques", so organizations are free to determine methods of monitoring, measurement, analysis and evaluation as long as the results are valid.	**8 Measurement, analysis and improvement** **8.1. General**
9.1.2. Customer satisfaction In addition to monitoring customer perception on whether the organization has met requirements, the organization now has to obtain information relating to customer views and opinions of the organization and its products and services.	**8.2.1. Customer satisfaction**
9.1.3. Analysis and evaluation Besides analysis, the new DIS includes evaluation. It also makes it clear what the purposes of analysis and evaluation are, stating that the output to be used for: - demonstrate conformity of products and services - assess and enhance customer satisfaction - ensuring conformity and effectiveness of the system - demonstrate that planning has been successful implemented - assess the performance of processes - assess the performance of external providers - determine the need and opportunities for improvement	**8.4. Analysis of data**
9.2. Internal audit The requirement for documented procedure has been deleted, otherwise the requirements are essentially the same.	**8.2.2. Internal Audit**
9.3. Management review The new DIS is more explicit to state that consideration of items to be reviewed include: - changes including external and internal issues relevant to the system, including its strategic direction - issues relating to external providers and other interested parties - adequacy of resources - effectiveness of actions taken to address risks and opportunities.	**5.6. Management review**

ISO/DIS 9001	ISO 9001:2008
10 Improvement Previous clause 8 has been divided between clauses 9 and 10. The version 2008 "preventive action" has been deleted because the DIS has included actions on risks and opportunities instead, which in essence is addressing potential nonconformities.	**8 Measurement, analysis and improvement**
10.1. General The new DIS has a greater emphasis on improvement, this being a whole clause on its own. This general sub-clause states that organizations have to determine and select opportunities for improvement and implement the necessary actions. Improvement includes improvement to process, product and quality management system results.	**8.1. General**
10.2. Nonconformity and corrective action This clause has two parts – first part on reaction to nonconformity and the second on preventing recurrence using corrective action process. For the first part, previously there was a clause only on actions to deal with nonconforming product but there was none which require actions on correcting nonconformity. The version 2008 clause 8.2.3. which requires correction and corrective actions when planned results are not achieve may be the closest to imply that corrections are required on nonconformities. For the second part, additional requirements include: - take action to control and correct nonconformity and deal with the consequences - determine if similar nonconformities exist or could happen - make changes to the quality management system, if necessary The note explains that in some instances, it can be impossible to totally eliminate the root cause and corrective action can reduce the likelihood of happening to an acceptable level.	**8.5.2. Corrective action**
10.3. Continual improvement Besides improving effectiveness of the quality management system, organizations also need to continually improve its suitability and adequacy. Continual improvement can be triggered by underperformance or identified opportunities. The DIS now requires the use of tools and methodologies for investigating underperformance and for supporting continual improvement.	**8.5.1. Continual improvement**