

FDIS 9001 – Quality Management Systems - Requirements

FDIS 9001 – Quality Management Systems- requirements was published on 09 July 2015 and supersedes DIS 9001. This document provides an overview to the differences between the two standards and is intended for users to enable an understanding of these differences.

FDIS 9001	DIS 9001	Comments and interpretations of differences
1. Scope	1. Scope	Minor change Minor changes to wording, for example removal of the word "continual" and addition of "service" but no fundamental changes to requirements or intent
2. Normative References	2. Normative References	Revised requirement Now refers to ISO 9000:2015 as a normatively referenced document and is indispensable for the application of FDIS 9001, note that this is the same approach as applied in ISO 9001:2008 A separate Comparison Document highlighting the differences between ISO 9000:2005 and FDIS 9000:2015 is available and should also be reviewed
3. Terms & Definitions	3. Terms & Definitions	Revised requirement See 2. Above, all terms and definitions have now been moved to ISO 9000:2015
4. Context of the Organisation	4. Context of the Organisation	No change
4.1 Understanding the organization and its context	4.1 Understanding the organization and its context	Minor change New note 1 states that issues can include positive and negative factors or conditions for consideration
4.2 Understanding the needs and expectations of interested parties	4.2 Understanding the needs and expectations of interested parties	Minor change Minor wording change, Impact changed to Effect intent unchanged
4.3 Determining the scope of the quality management system	4.3 Determining the scope of the quality management system	Minor change Minor changes to wording, for example "The organization shall apply all requirements of this international standard if they are applicable within the determined scope of its quality management system" – more explicit wording but no fundamental changes, intent unchanged
4.4 Quality management system	4.4 Quality management system	No change

and its processes	and its processes	
4.4.1		Revised requirement section now split into two sub clauses, slight changes in text in C) to determine "and apply", monitoring etc, d) now includes text "for the processes", f) address the risk, as determined added g) wording changed, intent unchanged
4.4.2		Minor change 4.4.2 a) & b) no change to intent, now separated out (documented information retain /maintain)
5. Leadership	5. Leadership	No change
5.1 Leadership and commitment	5.1 Leadership and commitment	No change
5.1.1 General	5.1.1 Leadership and commitment for the quality management system	Revised requirement Title change, reduction in points now a-j d) awareness now the "use" of process approach and "risk based thinking", the following has been removed - (previously k)ensuring the policy is communicated, understood and applied - rewording and renumbering from C) onwards, continual removed from improving
5.1.2 Customer focus	5.1.2 Customer focus	Minor change "Understood and consistently" added to a)
5.2 Policy	5.2 Quality policy	Minor change Title change only
5.2.1 Developing the quality policy		Revised requirement New heading for 5.2.1 , establish "Implement" now added, "Supports its strategic direction added to a), and reviewing removed from b)
5.2.2 Communicating the quality policy		Minor change New Heading, maintained now added – intent unchanged
5.3 Organizational roles, responsibilities and authorities	5.3 Organizational roles, responsibilities and authorities	Minor change reporting on the need for change or innovation has been removed, and especially for reporting to top management has changed to in particular to top management
6. Planning	6 Planning for the quality management	Minor change Title change only "for the quality management

	system	system" removed
6.1 Actions to address risks and opportunities	6.1 Actions to address risks and opportunities	No change
6.1.1	6.1.1	Revised requirement addition – "enhance desirable effects" now included and continual has been removed from improvement
6.1.2	6.1.2	Minor change New note (2) has been included, addresses opportunities or adoption of new practices, launch new products, open new markets etc.
6.2 Quality objectives and planning to achieve them	6.2 Quality objectives and planning to achieve them	No change
6.2.1	6.2.1	Minor change "Needed for the quality management system", added and "maintain" has replaced retain for documented information
6.2.2	6.2.2	No change
6.3 Planning of changes	6.3 Planning of changes	Minor change Slight wording change
7. Support	7. Support	No change
7.1 Resources	7.1 Resources	No change
7.1.1 General	7.1.1 General	No change
7.1.2 People	7.1.2 People	Minor change Simplified text, now includes the organization shall "determine" and provide.....implementation of its management system and for the operation and control, intent unchanged
7.1.3 Infrastructure	7.1.3 Infrastructure	Minor change The word necessary has been added + minor change to note. Intent unchanged

7.1.4 Environment for the operation of processes	7.1.4 Environment for the operation of processes	Minor change Expansion on notes only, further information provided as guidance
7.1.5 Monitoring and measuring resources	7.1.5 Monitoring and measuring resources	No change
7.1.5.1 General		Minor change New subtitle, Wording changed and strengthened in first paragraph - "and Provide" added intent unchanged
7.1.5.2 Measurement traceability		Minor change New subtitle, slight wording change, simplified, equipment has replaced instruments, calibrated or verified "or both" now added, appropriate action rather than corrective action, - intent unchanged
7.1.6 Organizational knowledge	7.1.6 Organizational knowledge	Minor change "and required updates" now added, notes added within the notes "it is gained by experience" has been added - rewording of notes
7.2 Competence	7.2 Competence	Minor change performance and effectiveness added to section, intent unchanged
7.3 Awareness	7.3 Awareness	Minor change slight wording change – "Persons doing work under the organization's control shall be aware of" has been changed to "The organization shall ensure that persons doing work under the organization's control are aware of", - intent unchanged
7.4 Communication	7.4 Communication	Revised requirement e) Who communicates has been added
7.5 Documented information	7.5 Documented information	No Change
7.5.1 General	7.5.1 General	No Change
7.5.2 Creating and updating	7.5.2 Creating and updating	No Change
7.5.3 Control of documented information	7.5.3 Control of documented information	No Change
7.5.3.1	7.5.3.1	No Change

7.5.3.2	7.5.3.2	Revised requirement last line added "Documented information retained as evidence of conformity shall be protected from unintended alternations"
8 Operation	8 Operation	No change
8.1 Operational planning and control	8.1 Operational planning and control	Revised requirement Reference expanded to clause 6 rather than just 6.1, b) has been split into b1) and b)2 e) "determining and keeping" and split into e1) and e2), now includes Note "Keeping"- intent unchanged
8.2 Requirements for products and services	8.2 Determination of requirements for products and services	Minor change Title change only "Determination of" now removed
8.2.1 Customer communication	8.2.1 Customer communication	Revised requirement No longer a requirement for a process - some wording changes, deletions and additional text to clarify Intent unchanged
8.2.2 Determining the requirements related to products and services	8.2.2 Determination of requirements related to products and services	Revised requirement Title change, requirements for processes have been removed, potential customers have been removed and the ability to meet the defined requirements have been removed, slight wording change to meet the claims, deletions and additional text to clarify sub clause a) now a1) a2)
8.2.3 review of requirements related to products and services	8.2.3 review of requirements related to products and services	No change
8.2.3.1		Revised requirement New sub clause, first sentence from 8.2.2 has been moved here and reworded, c) requirements specified by the organisation has been added, additional removed from statutory and regulatory. Note Added (same as 7.2.2 of 2008).
8.2.3.2		Minor change New sub clause, now more explicit, reworded but intent unchanged

8.2.4 Changes to requirements for products and services		Minor change New sub clause, now more explicit, reworded but intent unchanged
8.3 Design and development of products and services	8.3 Design and development of products and services	No change
8.3.1 General	8.3.1 General	Revised requirement Wording change, simplified, notes removed - intent unchanged
8.3.2 Design and development planning	8.3.2 Design and development planning	Revised requirement Expanded text now includes internal and external resources needed for design, the requirements for subsequent provision, the levels of control expected for the process by customers and other relevant interested parties, 8.3.2 e) has come from 8.3.3.d) and 8.3.2.i) has come from 8.3.3.f).
8.3.3 Design and development inputs	8.3.3 Design and development inputs	Revised requirement Slight wording change, new requirements - b) information derived from previous similar design and development activities and The organization shall retain documented information on design and development inputs.
8.3.4 Design and development controls	8.3.4 Design and development controls	Revised requirement Slight wording change, b) reviews are conducted to evaluate the ability of the results of design and development meet requirements, e) & f) are new requirements - any necessary actions are taken on problems determined during the reviews or verification and validation activities and documented information of these activities is retained, note added - intent unchanged
8.3.5 Design and development outputs	8.3.5 Design and development outputs	Revised requirement Slight wording change, new requirement in d) specify the characteristics of the product and services that are essential for their intended purpose. Also The organization shall retain the documented information resulting from the design and development process has been changed to The organization shall retain documented information on design and development outputs. - intent unchanged

8.3.6 Design and development changes	8.3.6 Design and development changes	Revised requirement Slight wording change and more explicit requirements for a) design and development changes b) the results of reviews c) the authorization of the changes d) the actions taken to prevent adverse impacts - intent unchanged
8.4 Control of externally provided processes, products and services	8.4 Control of externally provided products and services	Minor change Title change only to include processes
8.4.1 General	8.4.1 General	Revised requirement "shall determine the controls to be applied" more explicit also last paragraph – "these activities and any necessary actions arising from the evaluations." - intent unchanged
8.4.2 Type and extent of control	8.4.2 Type and extent of control of external provision	Minor change Title change and rewording - intent unchanged
8.4.3 Information for external providers	8.4.3 Information for external providers	Minor change d) external providers interactions with the organization, slight wording change f) or validation now included - intent unchanged
8.5 Production and service provision	8.5 Production and service provision	No change
8.5.1 Control of production and service provision	8.5.1 Control of production and service provision	Revised requirement Reworded, c) added "the implementation of" d) control of removed, environment added e) appointment of added, g) the implementation of actions to prevent human error - intent unchanged
8.5.2 Identification and traceability	8.5.2 Identification and traceability	Minor change Slight wording change, more focus on "outputs" - intent unchanged
8.5.3 Property belonging to customers or external providers	8.5.3 Property belonging to customers or external providers	Revised requirement Incorrectly used now removed, retain documented information on what has occurred now required, external providers property added in Note

8.5.4 Preservation	8.5.4 Preservation	Minor change Slight wording change, outputs was process, ensure was maintain, contamination control added in note - intent unchanged
8.5.5 Post-delivery activities	8.5.5 Post-delivery activities	Revised requirement potential undesired consequences replaces risk, customer requirements new
8.5.6 Control of changes	8.5.6 Control of changes	Minor change slight wording change, unplanned changes essential now replaced with control changes, specified removed, persons replaces personnel, necessary actions now includes additional text "arising from the review" - intent unchanged
8.6 Release of products and services	8.6 Release of products and services	Minor change Wording change, for verification of conformity removed, additional text has been added, expanding the last paragraph into a) & b) - intent unchanged
8.7 Control of nonconforming outputs	8.7 Control of nonconforming process outputs, products and services	Minor change Title changed to Control of Nonconforming outputs, now also split into sub clauses
8.7.1		Revised requirement New sub clause - Outputs remain, however products and services has been removed, corrective action replaced with action, This applies replaced with "This shall also apply", "or after" added, Obtaining authorization for use "as-is", release, continuation of re provision of the products and services - now reads "obtaining authorization for acceptance under concession" - intent unchanged
8.7.2		Revised requirement New sub clause - Documented information requirements now more prescriptive intent unchanged
9. Performance evaluation	9. Performance evaluation	No change
9.1 Monitoring, measurement, analysis and evaluation	9.1 Monitoring, measurement, analysis and evaluation	No change

9.1.1 General	9.1.1 General	Minor change Slight wording change, "needed" replaces "as applicable" - intent unchanged
9.1.2 Customer satisfaction	9.1.2 Customer satisfaction	Minor change requirements met changed to needs and expectations have been fulfilled, monitoring and reviewing now used, slight wording change, Note improved - intent unchanged
9.1.3 Analysis and evaluation	9.1.3 Analysis and evaluation	Revised requirement Slight wording change, "and other sources" removed, output now changed to results, assess the performance of processes has been removed, e) the effectiveness of actions taken to address risks and opportunities has been added, not now a requirement to provide as an input into management review - intent unchanged
9.2 Internal Audit	9.2 Internal Audit	No change
9.2.1	9.2.1	No change
9.2.2	9.2.2	Minor change Slight wording change reverting back to HLS core text, quality objectives, customer feedback and changes impacting the organisation have all been replaced with "changes affecting the organization, e) changed from necessary to appropriate intent unchanged
9.3 Management review	9.3 Management review	No change
9.3.1 General	9.3.1	Revised requirement Sub title added, re ordered to follow general, inputs and outputs, "and alignment with the strategic direction of the organization" has been added, rest of text moved to Management review inputs

9.3.2 Management review inputs		Revised requirement New sub title, now has a heading for Management Review Inputs - including strategic direction now resides in 9.3.1, customer satisfaction now also includes feedback from relevant interested parties, the extent to which quality objectives have been met is new, issues regarding external providers now relates to performance of external providers.
9.3.3 Management review outputs	9.3.2	Minor change Sub title added, now has a heading for Management Review outputs - slight wording change, continual changed to opportunities for improvement, resource needs separated out to a separate point. - intent unchanged
10. Improvement	10. Improvement	No change
10.1 General	10.1 General	Revised requirement Expanded text including address future needs and expectations, correcting, preventing or reducing undesired effects has been added and note revised
10.2 Nonconformity and corrective action	10.2 Nonconformity and corrective action	No change
10.2.1	10.2.1	Revised requirement slight wording change back to HLS core text now requires b1) addition of and analysing, e) update risk and opportunities determined during planning if necessary - new requirement - Notes removed
10.2.2	10.2.2	No change
10.3 Continual improvement	10.3 Continual improvement	Minor change Slight wording change, simplified text, requirements regarding tools and methodologies removed - intent unchanged

It should also be noted that there are changes in Annex A & B of FDIS 9001 when comparing against Annex A & B of DIS 9001, of particular note are the following:

1. Annex A.3 now concentrates specifically on understanding the needs and expectations of interested parties (Clause 4.2) rather than the overall subject of context of the organisation (Clause 4)
2. Detail regarding the quality management principles that was previously in annex B has now been moved to section 2 of ISO 9000: 2015 whilst an overview is given in the introduction of FDIS 9001 (section 0.2).