**ISO 9001:2015(IS) –Transition checklist**

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| ***General Information*** | | |
| Company Name | : |  |
| Project No. | : |  |
| Standard | : | **ISO 9001:2015(IS)** |
| Review Done By | : |  |
| Review Date | : |  |

**The use of this checklist:**

This transition checklist highlights the changes in the standard compared with the 2008-version and is not intended to cover all requirements of the new standard. It is intended to be a support for the auditor during the transition audit and shall also be kept as a formal record from the transition audit as evidence of verification. The checklist is based on the IS version. From the IS version to the published standard only editorial changes are expected and allowed. Therefore it is allowed to do a transition audit based on IS. This document will be updated for the upcoming publication of the standard. The checklist is mandatory for use for a transition audit. However it is also intended for use as a support for other customer activities like GAP-analysis etc.   
The checklist content is based on the documents “IS 9001:2015 and High Level Structure **–** Explanation of changes” and “HLS and ISO 9001/ISO 14001 - Key changes and transition”, both available from the [MSC site](http://groups.dnv.com/sites/BA_Service_Portal/SitePages/MSC.aspx) of the Service Portal.

**Minimum documentation requirements:**

As a support for the auditor/user the attached document shows the minimum documentation required by the new standard.



| ***Changes*** | | | |
| --- | --- | --- | --- |
| ***Clause*** | ***Items reviewed*** | ***Result OK? (Yes/No)*** | ***Document / information reference*** |
| 4.1 [Understanding of the organization and its context] | Has the organization determined 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?  Is information on changes in the context systematically presented in the Management Review?  Have they been considered as inputs for scope definition and identification of risks and opportunities?  How does organization monitor and review the information about these external and internal issues?  *Additional guidance notes: Will this be a recurring, repeatable and transparent process? Is the information documented? (Note that documented information is not explicitly required, but may be beneficial to ensure an effective process)*  *Evidence of proper determination could e.g. be in minutes of meetings, strategic analysis, SWOT analysis etc. depending on the complexity of the organization.* | ***Yes/No*** | *ref.* |
| 4.2 [Understanding the needs and expectations of interested parties] | Has the organization determined the following?   1. The interested parties that are relevant to the quality management system; 2. The requirements of these interested parties that are relevant to the quality management system.   Is information on changes in the context systematically presented in the Management Review?  Have they been considered as input for scope definition and identification of risks and opportunities?  How does organization monitor and review the information about the interested parties and the relevant requirements?  *Additional guidance notes: What is the process and how is the info effectively collected, presented and used within the organization?*  *Will this be a recurring, repeatable and transparent process? Is the information documented? Evidence of proper determination and review may e.g. documented in a table listing various stakeholders and corresponding needs and expectations (requirements). Note that documented information is not explicitly required, but may be beneficial to ensure an effective process* | ***Yes/No*** | *ref.* |
| 4.3 [Determining the scope of the quality management system] | Is scope of the QMS *documented* and does it state products and services and justification for any claims of non-applicable requirements? | ***Yes/No*** |  |
| 4.4 [Quality management system and its processes] | Has the organization determined the processes needed for the QMS and (underlined items are new): “  a) determined the inputs required and the outputs expected from these processes;  b) determined the sequence and interaction of these processes;  c) determined an applied the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation, and control of these processes;  d) determined the resources needed and ensure their availability;  e) assigned the responsibilities and authorities for these processes;  f) addressed the risks and opportunities as determined in accordance with the requirements of 6.1,  g) evaluated these processes and implemented any changes needed to ensure the processes achieve their intended results;  h) improved the processes and the quality management system.  “  How does the organization maintain *documented* information to the extent necessary to support the operation of processes and retain documented information to the extent necessary to have confidence that the processes are being carried out as planned. | ***Yes/No*** |  |
| 5.1.1  [Leadership and commitment - General] | How does top management demonstrate leadership and commitment with respect to the quality management system?  Do they take an active and leading role and understand their duties in relation to the QMS and are participating in promoting and supporting effective quality management?  Refer list in 5.1.1 and note especially these new items:   * Taking accountability of the effectiveness of the QMS * Connection to strategic direction * Integration of requirements into the organization’s business processes. * Promoting awareness of process approach and risk based thinking * Engaging, directing and supporting persons to contribute to the QMS   (Guidance notes: Evidence of leadership can be shown e.g. through verification of:   * Strategy documents, policies, business plans/objectives, including deployment and progress reporting,(i.e. clear direction) * Involvement in objective setting, performance evaluation and follow-up * Records of meetings, action lists, and various means of repeated communications (e.g. e-mails, meetings with all employees), * Clearly defined and understood responsibilities and authorities * Broad and active involvement from top management in management reviews and other management forums where QMS is on the agenda (inspiring/motivating activities) | ***Yes/No*** | *ref.* |
| 5.２  [Quality policy] | Is the quality policy compatible with strategic direction and the context of the organization? (5.1.1 b) | ***Yes/No*** | *ref.* |
| 6.1 - 6.1.1  [Actions to address risks and opportunities] | Can the organisation demonstrate a systematic approach that enables them to effectively identify risks and opportunities and to define actions as input to the planning of their QMS?  Has the organization considered the external and internal issues and the requirements of the interested parties when determining the risks and opportunities?  (See also 4.4 for the embedding R&O into the QMS and its processes.) | ***Yes/No*** | *ref.* |
| 6.1 - 6.1.2  Actions to address risks and opportunities] | How has the organization integrated and implemented the actions for risks and opportunities into its quality management system processes?  How do they evaluate the effectiveness of these actions? | ***Yes/No*** | *ref.* |
| 6.2.1  [(The organization shall establish quality objectives.)] | Does the organization establish quality objectives at relevant functions, levels and processes?  Are the quality objectives compatible with the strategic direction and the context of the organization? (5.1.1 b))  Are the quality objectives as below?:   1. be consistent with the quality policy, 2. be measurable; 3. take into account applicable requirements; 4. be relevant to conformity of products and services and the enhancement of customer satisfaction; 5. be monitored; 6. be communicated; 7. be updated as appropriate.   Do they retain documented information on the quality objectives? | ***Yes/No*** | *ref.* |
| 6.2.2  [(When planning how to achieve its quality objectives, the organization shall determine.)] | To achieve its quality objectives, does the organization determine the followings?   1. what will be done; 2. what resources will be required; 3. who will be responsible; 4. when it will be completed; 5. how the results will be evaluated.   Can they demonstrate the whole cycle of objectives setting according to the above? | ***Yes/No*** | *ref.* |
| 6.3  [Planning of changes] | Where the organization determines the need for change to the quality management system (see 4.4), is the change carried out in a planned and systematic manner?  Does the organization consider the following:   1. the purpose of the change and their potential consequences; 2. the integrity of the QMS; 3. the availability of resources; 4. the allocation or reallocation of responsibilities and authorities. | ***Yes/No*** | *ref.* |
| 7.1.6  [Organizational knowledge] | How does the organization determine and maintain the knowledge necessary to address changing needs and trends and for the operation of its processes and to achieve conformity of products and services? | ***Yes/No*** | *ref.* |
| 7.4  [Communication] | How does the organization determine the internal and external communications relevant to the quality management system including:   1. on what it will communicate; 2. when to communicate; 3. with whom to communicate; 4. how to communicate; 5. who communicates | ***Yes/No*** | *ref.* |
| 8.1  [Operational planning and control] | How does the organization control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary?  (Note also connection to 4.4 related to retaining documented information to the extent necessary to have confidence that the processes have been carried out as planned and to demonstrate conformity of products and services to requirements. How has the organization decided the extent?) | ***Yes/No*** | *ref.* |
| 8.4.1 -8.4.2  [Control of externally provided processes, products and services] | How does the organization determine the controls to be applied to externally provided processes, products and services when:   1. products and services from external providers are intended for incorporation into the organization’s own products and services; 2. products and services are provided directly to the customer(s) by external providers on behalf of the organization; 3. a process or part of a process is provided by an external provider as a result of a decision by the organization   Has the organization sufficiently determined needed controls to be applied to external provisions of processes and products/services taking into consideration:   1. the potential impact of the external provisions on the organization’s ability to meet customer and regulatory requirements 2. the effectiveness of the controls applied by the external provider   Does the organization establish and apply criteria for the evaluation, selection, monitoring of performance and re-evaluation of the external providers based on their ability to provide processes or products and services in accordance with specified requirements?  Do they retain appropriate documented information of the results of the evaluations, monitoring of performance and re-evaluations of external providers? | ***Yes/No*** | *ref.* |
| 8.5.5  [Post-delivery activities] | When post-delivery activities apply for the organization:  In determining the extent of post-delivery activities that are required, does the organization consider the following?:   1. statutory and regulatory requirements. 2. the potential undesired consequences associated with the products and services; 3. the nature, use and intended lifetime of the products and services; 4. customer requirements 5. customer feedback;   (Guidance note: As minimum the organization need to control its contractual and statutory/regulatory post-delivery obligations. Post-delivery activities beyond this is at the discretion of the organization.) | ***Yes/No*** | *ref.* |
| 8.5.6  [Control of changes] | Does the organization review and control changes for production or service provision to the extent necessary to ensure continuing conformity with specified requirements?  Does the organization retain documented information describing the results of the review of changes, the personnel authorizing the change, and any necessary actions | ***Yes/No*** | *ref.* |
| 9.1.1  [General (Monitoring, measurement, analysis and evaluation)] | Are the following items determined?   1. what needs to be monitored and measured; 2. the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results; 3. when the monitoring and measuring shall be performed; 4. when the results from monitoring and measurement shall be analysed and evaluated.   Does the organization evaluate the performance and the effectiveness of the QMS?  (see also 9.1.3 “Analysis and evaluation” below)  Does the organization retain documented information as evidence of the results? | ***Yes/No*** | *ref.* |
| 9.1.3 [Analysis and evaluation] | Does the organization analyze and evaluate appropriate data and information arising from monitoring and measurements?  Are results of the analysis 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 successfully implemented;  e) the effectiveness of actions taken to address risks and opportunities ;  f) the performance of external provider(s);  g) the need for improvements to the quality management system.  Are the results of analysis and evaluation used to provide inputs to management review? |  |  |
| 9.3  [Management review] | Is the management review planned and carried out taking into consideration of the followings (new items underlined):   1. the status of actions from previous management reviews; 2. changes in external and internal issues that are relevant to the quality management system; 3. information on the quality performance, including trends for:    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; 4. the adequacy of resources 5. the effectiveness of actions taken to address risks and opportunities (see 6.1); 6. opportunities for improvement.   (See also 9.1.3 “Analysis and evaluation”) | ***Yes/No*** | *ref.* |