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 Our ref

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**To the Members of**

**ISO/TC 176/SC 2 -**

**Quality Management and**

**Quality Assurance/**

**Quality Systems**

**Analysis of the changes to Annex SL, Appendix 2, versus ISO 9001:2015**

The document given below has kindly been prepared by the ISO/TC 176/SC2 experts to the JTCG/TF14.

It gives a brief analysis of each of the changes to Annex SL Appendix 2 (the ISO "High Level Structure" for management system standards, also referred to as draft Guide 83) that have recently been approved by an ISO/TMB Member Body ballot (see document SC2/N1538), against the possible risks and benefits these may have for ISO 9001:2015.

SC2 National Standards member bodies may find consideration of this document helpful when deciding their response to the current systematic review of ISO 9001:2015, which is due to close in December.

We are grateful to those experts for having prepared this for us.

Yours sincerely

Charles Corrie
for the BSI Secretariat of
ISO/TC 176/SC 2

ISO Guide 83 (Annex SL) Changes to be Considered in a Future Revision to ISO 9001

September 18, 2020

ISO TC176/SC2/TG01 Report by Lorri Hunt / Jose Dominguez

This analysis includes a summary of the changes to Annex SL as published in Guide 83. The changes have been compared to current text in ISO 9001:2015 and a determination made of the impact, benefit, and any changes that potentially would need to be made. Criteria for Low and High Impact and High and Low Benefit are included. The determination of impact and benefit may be subjective, but the change that might be required would remain the same since it is text in Annex SL.

Where ISO 9001:2015 includes a requirement that is not in Guide 83, an analysis of changes that might need to be considered based on other changes made have been included.

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| **Low Impact**  | **High Benefit** |
| * ISO 9001 already includes the text.
* Change of title.
* Change is editorial or the change would require no or little change by users.
 | * The change matches current text in ISO 9001 and eliminates the need for a deviation.
* The change addresses a known issue with ISO 9001 with translation or understanding of requirements.
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| **High Impact** | **Low Benefit** |
| * The change would require a substantial change to the structure of ISO 9001.
* The change could require users to make a change to their QMS
 | * The change to structure does not improve understanding of the requirement.
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| **Clause** | **Change in Guide 83** | **Potential Impact to ISO 9001** |
| General | Is Available as documented informationdocumented information shall be available as evidence | Medium Impact / High BenefitA change has been made throughout Guide 83 to address inconsistency between MSS in the application of is available, and maintain and retain documented information.For many languages, there is no difference between maintain and retain, therefore an approach was developed which eliminates the need for these words.Guide 83 now uses is available as documented information. Because there are requirements for documented information, the organization would need to meet the requirements in clause 7.5.Where Guide 83 uses “documented information shall be available as evidence,” this is what most organizations would typically refer to as records. |
| 4.1 | Changed outcome to resultsability to achieve the intended ~~outcome~~ result(s) of its XXX management system | No impact / High BenefitISO 9001:2015 currently uses result(s). This eliminates the need for a deviation. |
| 4.2 | A new requirement to be determined has been added:*which of these requirements will be addressed through the XXX management system.*  | Low impact / High BenefitISO 9001:2015 currently addresses this as a lead-in sentence to the requirement “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”Consider whether this phrase should be added to the new requirement |
| 4.3 | No changes to Guide 83 | Low Impact / High BenefitISO 9001:2015 currently added “and be maintained as documented information.”Documented information needs to be consistent throughout the standard. |
| 4.4 | No changes to Guide 83 | No Impact |
| 5.1 (5.1.1) | Changed outcome to resultsensuring that the XXX management system achieves its intended ~~outcome r~~esult(s) | Low impact / High BenefitISO 9001:2015 currently uses result(s). This eliminates the need for a deviation. |
| 5.1.2 |  | Unique clause to ISO 9001 – no impact |
| 5.1 | supporting other relevant ~~managerial~~ roles to demonstrate their leadership as it applies to their areas of responsibility. | Low impact to drafters. / Medium BenefitThere might be impact to users. |
| 5.2 | XXX Policy | Low impact since xxx policy is used in the text. / Low Benefit |
| 5.2.1 c) | includes a commitment to ~~satisfy~~ meet applicable requirements; | Low impact / Low Benefit |
| 5.3 | No Changes to Guide 83 | No Impact |
| 6.1 (6.1.1) | Change outcome to resultsgive assurance that the XXX management system can achieve its intended ~~outcome~~ result(s) | No impact / High BenefitISO 9001:2015 currently uses result(s). This eliminates the need for a deviation. |
| 6.2 | f)g) be available as documented information. ~~The organization shall retain documented information on the XXX objectives.~~ | Change to textLow Impact / High BenefitMoved from standalone sentence to bullet item. (No impact)ISO 9001:2015 had changed retain to maintain. The use of documented information has been changed throughout the standard. See General comment on this topic. |
| 6.3 | Guide 83 added a clause on Planning of changes | No Impact / High BenefitISO 9001:2015 already included this clause. The only difference is that a reference to clause 4.4 is issued in the introduction section. ISO 9001:2015 also includes a list of items to be considered that is not in Guide 83. |
| 7.1 (7.1.1) | No Change to Guide 83. | No impact |
| 7.1.2 |  | Unique clause to ISO 9001:2015 – No impact |
| 7.1.3 |  | Unique clause to ISO 9001:2015 – No impact |
| 7.1.4 |  | Unique clause to ISO 9001:2015 – No impact |
| 7.1.5.1 |  | Unique clause to ISO 9001:2015ISO 9001 refers to “retain appropriate documented information as evidence….” This language should be reviewed to ensure consistency with revised references to documented information. |
| 7.1.5.2 |  | Unique clause to ISO 9001:2015 – No impact |
| 7.1.6 |  | Unique clause to ISO 9001:2015 – No impact |
| 7.2 | ~~retain appropriate documented information as evidence of competence~~. Appropriate documented information shall be available as evidence of competence. | Change to text.Low impact / High BenefitSee general comment. Available as evidence is similar to retain.  |
| 7.3 | No change to Guide 83 | No impact |
| 7.4 | No change to Guide 83 | No impact |
| 7.5.1 | No change to Guide 83 | No impact |
| 7.5.2 | 7.5.2 Creating and updating documented information | No impactAdding documented information to the title does not change the intent of the requirement. |
| 7.5.3 (7.5.3.1) | No change to Guide 83 | No impact |
| 7.5.3 (7.5.3.2) | No change to Guide 83 | No impact |
| 8.1 | The organization shall plan, implement and control the processes needed to meet requirements, and to implement the actions determined in Clause 6.~~1~~, by: | No impact / High BenefitISO 9001:2015 already referred to Clause 6. This eliminates the need for a deviation. |
| 8.1 | ~~keeping documented information to the extent necessary to have confidence that the processes have been carried out as planned.~~ Documented information shall be available to the extent necessary to have confidence that the processes have been carried out as planned. | Change to text.Low impact / High BenefitISO 9001:2015 already has a requirement related to documented information and confidence that processes have been carried out as planned. The new statement does not include 8.1.e)2) |
| 8.1 | The organization shall ensure that ~~outsourced~~ externally provided processes, products or services that are relevant to the XXX management system are controlled. | Change to text.Low Impact / High BenefitNo impact to ISO 9001:2015 requirements as externally provides processes, products and services is already used. |
| 8.2.1 |  | Unique clause to ISO 9001:2015 – No impact |
| 8.2.2 |  | Unique clause to ISO 9001:2015 – No impact |
| 8.2.3.1 |  | Unique clause to ISO 9001:2015 – No impact |
| 8.2.3.2 |  | Unique clause to ISO 9001:2015 8.2.3.2 b) refers to documented information. The text should be reviewed to ensure consistency. See General comment. |
| 8.2.4 |  | Unique clause to ISO 9001:2015 – No impact |
| 8.3.1 |  | Unique clause to ISO 9001:2015 – No impact |
| 8.3.2 |  | Unique clause to ISO 9001:2015 8.3.2.j refers to documented information. The text should be reviewed to ensure consistency. See General comment. |
| 8.3.3 |  | Unique clause to ISO 9001:2015 The last sentence refers to documented information. The text should be reviewed to ensure consistency. See General comment. |
| 8.3.4 |  | Unique clause to ISO 9001:2015 8.3.4.f refers to documented information. The text should be reviewed to ensure consistency. See General comment. |
| 8.3.5 |  | Unique clause to ISO 9001:2015 The last sentence refers to documented information. The text should be reviewed to ensure consistency. See General comment. |
| 8.3.6 |  | Unique clause to ISO 9001:2015 This clause refers to documented information. The text should be reviewed to ensure consistency. See General comment. |
| 8.4.1 |  | Unique clause to ISO 9001:2015 The last paragraph refers to documented information. The text should be reviewed to ensure consistency. See General comment. |
| 8.4.2 |  | Unique clause to ISO 9001:2015 – No impact |
| 8.4.3 |  | Unique clause to ISO 9001:2015 – No impact |
| 8.5.1 |  | Unique clause to ISO 9001:2015 – No impact |
| 8.5.2 |  | Unique clause to ISO 9001:2015 The last paragraph refers to documented information. The text should be reviewed to ensure consistency. See General comment. |
| 8.5.3 |  | Unique clause to ISO 9001:2015 The last paragraph refers to documented information. The text should be reviewed to ensure consistency. See General comment. |
| 8.5.4 |  | Unique clause to ISO 9001:2015 – No impact |
| 8.5.5 |  | Unique clause to ISO 9001:2015 – No impact |
| 8.5.6 |  | Unique clause to ISO 9001:2015 The last paragraph refers to documented information. The text should be reviewed to ensure consistency. See General comment. |
| 8.6 |  | Unique clause to ISO 9001:2015 This clause refers to documented information. The text should be reviewed to ensure consistency. See General comment. |
| 8.7.1 |  | Unique clause to ISO 9001:2015 – No impact |
| 8.7.2 |  | Unique clause to ISO 9001:2015 This clause refers to documented information. The text should be reviewed to ensure consistency. See General comment. |
| 9.1 (9.1.1) | ~~The organization shall retain appropriate~~ D~~d~~ocumented information shall be available as evidence of the results | Change of text.Low impact / High BenefitISO 9001:2015 currently has this labeled as General with an additional clause for analysis and evaluation (9.1.3) |
| 9.1.2 |  | Unique clause to ISO 9001:2015 – No impact |
| 9.1.3 |  | Unique clause to ISO 9001:2015 – No impact |
| 9.2.1 | 9.2.1 General | Change to text.Low Impact / High BenefitISO 9001:2015 already had the section identified as 9.2.1. The title General needs to be added. |
| 9.2.2 | 9.2.2 Internal audit programme | Change to text.Low Impact / High BenefitISO 9001:2015 already had the section identified as 9.2.2. The title Internal Audit Programme needs to be added. |
| 9.2.2 | ~~The organization shall:~~ The organization shall plan, establish | Change to formatting.Low impact/ Low Benefit |
| 9.2.2 | a) define the audit objectives, criteria and scope for each audit; | Added the word objectives. Low impact / Low Benefit |
| 9.2.2 | ~~retain~~ d) Documented information shall be available as evidence of the implementation of the audit programme(s) and the audit results | Change to text.Low Impact / High Benefit1. Change to documented information. See General
2. Outcomes changed to results – ISO 901:2015 already uses results.
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| 9.3.1 | 9.3.1 General | Change to text / headingLow Impact / High BenefitISO 9001:2015 already has a clause 9.3.1 General |
| 9.3.2 | 9.3.2 Management review inputs | Change to text / headingLow Impact / High BenefitISO 9001:2015 already has a clause 9.3.2 Management Review Inputs |
| 9.3.2 | ~~The management~~ The management review shall include ~~consideration of:~~ | Change to TextLow Impact / Medium BenefitThis change was made to address the comment that consider made the inputs optional. TC176/SC2 comment |
| 9.3.2 | changes in needs and expectations of interested parties that are relevant to the XXX management system; | This is a new requirement.Medium impact / Medium BenefitISO 9001 includes a requirement for monitor and review of needs and expectations of relevant interested parties in 4.2. 9.3.2 currently includes a requirement under c) 1) customer satisfaction and feedback from relevant interested parties.Review clause 4.2 and 9.3.2 for consistency based on this change. |
| 9.3.3 | 9.3.3 Management review results | Change to text / headingLow Impact / High BenefitISO 9001:2015 already has a clause 9.3.3 Management review outputs. For consistency, the clause title would need to be revised. |
| 9.3.3 | ~~The organization shall retain~~ D~~d~~ocumented information shall be available as evidence of the results of management reviews. | Change to textLow Impact / High BenefitsThis clause refers to documented information. The text should be reviewed to ensure consistency. See General comment. |
| 10.1 (ISO 9001) | No Guide 83 requirement | The general requirement is still not included in Guide 83. Consider the changes to structure. |
| 10.1 | Continual Improvement | Change to order of clausesHigh impact / Low benefitMoved from 10.2. ISO 9001:20915 includes clause 10.1 General. This clause was not added. The change in sequence does not change the requirements but requires a different sequence to be considered. |
| 10.2 | Nonconformity and Corrective Action | Change to order of clausesHigh impact / Low benefitMoved from 10.1. ISO 9001:20915 includes this clause as 10.2 at this time so there are no issues. |