

# A Sneak Peek at the New Draft of ISO 9001:2015

## 新版 ISO 9001:2015 草案率先解構

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The next version of *ISO 9001 (Quality Management Systems – Requirements)* will soon proceed to the DIS (Draft International Standard) stage, after a significant vote of approval of the Committee Draft that was circulated for ballot and comment among ISO Member Bodies in 2013. The Working Group responsible for the revision process met in November 2013 and again in March 2014 to address the various comments received, and the DIS is expected to be published in May this year. The DIS still does not represent the final version of the new standard, however, which will undergo at least one more round of comment and voting within the ISO consensus-building process, but it does signify the first time that the draft has been made available for access by all users outside of the ISO technical community.

### More in line with modern business practices

As Chair of ISO/TC176/SC2, the ISO subcommittee responsible for ISO 9001 and ISO 9004 (among other standards), I am very excited about this revision, which aims to update ISO's flagship standard to be more in line with modern business practices. Some of the improvements that are being incorporated are as follows:

- ISO 9001:2015 will use the new harmonised High Level Structure that has been developed by ISO's Joint Technical Coordination Group, and published in Annex SL of the ISO Directives (available for free download from <http://www.iso.org/sites/directives/directives.html>). This will make life easier for organisations that choose to have a single ("integrated") management system to meet the requirements of multiple standards such as ISO 9001 (Quality), ISO 14001 (Environmental), ISO 27001 (Information Security) and the future ISO 45001 for Health and Safety Management Systems (which is expected to replace OHSAS 18001), among others.
- We are placing much more emphasis on the service sector, by making the overall language of the standard more user-friendly for service organisations, and adapting some of the traditional clauses to focus more on the needs of the service sector. Not only have we given more attention to requirements related to service design and development, and "measuring equipment" as it relates to the service sector, but the standard will now specifically use the terminology "products and services" instead of just "products", as before.
- We are maintaining a strong emphasis on the "Process Approach" that has been so successful in the 2000 and 2008 versions of the standard, whereby an organisation needs to manage its processes in order to achieve the desired outcomes (which, in the case of ISO 9001, means providing customers with "consistent, conforming products").
- Interwoven into the new standard is a focus on "risk-based thinking", whereby an organisation needs to identify the risks (and opportunities!) associated with its activities, and take actions to mitigate the risks of generating non-conforming products (including, of course, services). All processes needed for the quality management system have to be managed using the Plan-Do-Check-Act cycle, but some need a higher degree of control than others if they are to contribute to the organisation's ability to meet its objectives. It is not the intention of ISO 9001:2015 to require all organisations to adopt formal risk management methodologies, but rather to provoke a mentality of "risk-based thinking". Put simply, this means considering risk qualitatively (and, depending on the organisation's context, quantitatively) when defining the rigour and degree of formality needed when planning and controlling individual activities and processes.

過去一年，ISO（國際標準化組織）已為新版本《ISO 9001 質量管理體系——要求》的「委員會草案」完成各單位的傳閱及意見收集，並取得投票通過；而負責改版的工作小組亦分別於去年 11 月及今年 3 月舉行會議，討論收集到的建議。預計「國際標準草案」將會於 5 月出版，標誌著新版本將初次向全球用家亮相。其後，最快只要再經過多一輪意見收集和投票，得到 ISO 內部各界的共識，最終的新版本便能正式出台。

### 與今日營商模式更為接軌

經過修改後，新版本的 ISO 9001 與今日的營商模式更為接軌。作為專責 ISO 9001 及 ISO 9004 等標準的 ISO/TC176/SC2 技術委員會主席，本人對此實深感振奮。以下列出一些修訂的重點：

- 新修訂版的 ISO 9001 將會以 ISO 聯合技術協調小組編寫的「高階架構」及「相同文本」方式編寫，並作為《ISO 指引》中的「附件 SL」出版（可在此免費下載：<http://www.iso.org/sites/directives/directives.html>），更方便機構能透過實行一個綜合管理體系，同時達到多個標準（包括《ISO 9001 質量管理體系》、《ISO 14001 環境管理體系》、《ISO 27001 信息安全管理体系》、將取代 OHSAS 18001 的《ISO 45001 健康和安全管理體系》等）。
- 為了讓服務業更易掌握，新版本對相關的詞彙和內容進行修改，例如補充了「服務設計及開發」和「量度工具」的要求，以及把「產品」一詞擴闊為「產品及服務」等。
- 更強調「過程方法」的實行。「過程方法」即透過管理過程以取得理想的效果（在 ISO 9001 中，即為客戶提供「質素穩定和合格的產品」），其應用在 ISO 9001 的 2000 和 2008 年版本取得了顯著的成效。
- 將「風險管理思維」貫通整個管理體系，要求機構了解其活動所涉及的風險（及機遇），並儘可能降低生產出不合格產品（及服務）的風險。雖然，現時質量管理體系的所有過程已按「策劃—執行—檢查—行動」的模式執行，但為了達到更高的目標，某些過程應受到更嚴謹的監控。其實新版 ISO 9001 並非要求所有機構實行正式的風險管理措施，而是推廣「風險管理思維」，即「質性」地管理風險（某些機構則是「定量」地管理），並在規劃及監控個別活動及過程的時候，調整風險管理的力度和形式。



## Structure of the new version

The structure of the new version of ISO 9001 will follow the following overall “Annex SL” sequence:

<b>1. Scope 範圍</b>	<b>7. Support 支援</b> <ul style="list-style-type: none"> <li>Resources 資源</li> <li>Competence 員工能力</li> <li>Awareness 員工意識</li> <li>Communication 溝通</li> <li>Documented information 文件記錄</li> </ul>
<b>2. Normative references 引用標準</b>	
<b>3. Terms and definitions 詞彙和定義</b>	
<b>4. Context of the organisation 機構環境</b> <ul style="list-style-type: none"> <li>Understanding the organisation and its context 了解機構及其環境</li> <li>Needs and expectations of interested parties 相關利益團體的需求和期望</li> <li>Determining the scope 決定管理體系的範圍</li> <li>Management System 管理體系</li> </ul>	<b>8. Operation 營運</b> <ul style="list-style-type: none"> <li>Operational planning and control (This is where most of the requirements of the current Clause 7 of ISO 9001:2008 will be incorporated) 營運規劃與監控 (舊版中「條文7」的大部分內容將會轉移至此)</li> </ul>
<b>5. Leadership 領導</b> <ul style="list-style-type: none"> <li>Leadership and commitment 領導與承擔</li> <li>Policy 方針</li> <li>Roles, responsibility and authority 職能、職責與權限</li> </ul>	<b>9. Performance evaluation 績效評估</b> <ul style="list-style-type: none"> <li>Monitoring, measurement, analysis and evaluation 監察、測量、分析與評估</li> <li>Internal audit 內部審核</li> <li>Management review 管理評審</li> </ul>
<b>6. Planning 規劃</b> <ul style="list-style-type: none"> <li>Actions to address risks &amp; opportunities 應對風險和機會的措施</li> <li>Objectives and plans to achieve them 目標和計劃實行</li> </ul>	<b>10. Improvement 改進</b> <ul style="list-style-type: none"> <li>Non conformity and corrective action 不符合項與糾正措施</li> <li>Continual Improvement 持續改進</li> </ul>

## 新修訂版的章節結構

新修訂版 ISO 9001 是按照「附件 SL」所列的章節結構編寫，詳細如下：

## Other important revisions

### • No specific requirement in ISO 9001:2015 for a “Management representative”

Of course this does not mean that all Management Representatives will need to start looking for a new job! Their role in coordinating the deployment of the system between the various functions and levels of the organisation will remain an important one. In the past, though, we have found that the top management of some organisations have effectively abdicated their responsibility for the providing leadership regarding the quality management system to the “MR”. ISO 9001:2015 will place more requirements on “top management”, with a focus on ensuring *they* provide leadership at all levels throughout the organisation. ISO 9001:2015 will provide some flexibility in the way in which top management may choose to delegate *some* of the responsibilities for the system and reporting back on its performance, whilst at the same time maintaining overall responsibility for themselves.

### • No more requirement for a “Quality Manual”

Many organisations today have their quality management systems housed on their company intranet, and integrated with other components such as environmental or health and safety management. ISO 9001:2015 will therefore no longer require a specific “Quality Manual”, though in some economic sectors this may continue to be a customer or sector-specific requirement. Equally, if some organisations find it to be of benefit to maintain their Quality Manuals, because of their own specific context, they will be perfectly entitled to do that.

### • No more separate clause on “Preventive action”

This change was made intentionally, and should not be taken to imply that preventive action is no longer important – quite the contrary! The overall focus of a quality management system should be on preventing problems and this idea is now incorporated throughout the standard in the “risk-based thinking” approach mentioned earlier, whereby risks should be taken into consideration on an ongoing basis, and subject to mitigation wherever necessary to prevent nonconforming products or services. We have also noticed in the past that there is a poor understanding in many organisations about the difference between “correction”, “corrective action” and “preventive action”, and the wording of ISO 9001:2015 has been simplified to try to address this. In Clause 10 of the new standard, the organisation will be required to:

- react to the nonconformity, and as applicable:
  - take action to control and correct it and deal with the consequences
- evaluate the need for action to eliminate the causes of the nonconformity, in order that it does not recur or occur elsewhere, by
  - reviewing the nonconformity
  - determining the causes of the nonconformity, and
  - determining if similar nonconformities exist, or could potentially occur

Finally, there will be time for users to make any adjustments necessary to their quality management system – a three-year transition period has already been agreed with ISO/CASCO and the IAF, after publication of the new version, during which certifications to ISO 9001:2008 will continue to be recognised.

## 其他重要修訂

### • 不再需要指定的「管理者代表」

當然，現時的管理者代表不會因此失業的！他們仍需要於各部門維持管理體系的運行，只是在舊有的模式中，我們發現某些機構的領導層把管理體系的責任交給管理者代表全權處理，較少領導他們的工作；而新修訂版則對領導層有更多要求，確保他們領導機構各階層推行工作。不過，新修訂版會容許領導層將部分責任委託給其他人員，但仍須承擔機構整體的監督和領導工作。

### • 不再需要「品質手冊」

現今許多機構已將質量管理體系的資料上傳至公司內聯網，並融入環保或職安健管理等其他元素，因此新修訂版不再要求機構製作一本實質的「品質手冊」。當然，某些機構基於行業、客戶或個別的需要，仍可選擇製作。

### • 不再有「預防措施」的獨立條文

這並非說預防措施不再重要！相反，「如何預防問題發生」已經成為新修訂版ISO 9001的焦點，而「預防措施」則融入「風險思維」的概念中，要求機構在整個管理體系均加入風險的考量，並儘可能避免生產出不合格產品及服務的情況。另外，過去我們發現不少機構會把「糾正」、「糾正措施」、「預防措施」等詞彙混淆，因此新修訂版已把這些詞彙簡化了。以下是新版中「條文10」所列出的要求：

- 如發生不符合項，應進行處理；必要時應：
  - 進行控制及糾正措施，並處理其引致的後果
- 評估是否需要消除「不符合項」的問題根源，以防止問題再次發生或導致更多其他問題。所需程序包括：
  - 審視不符合項的細節
  - 判斷發生的原因
  - 判斷是否存在或有可能出現其他類似的不符合項

最後，ISO 合格評定委員會 (ISO/CASCO) 及國際認可論壇 (IAF) 已通過新版推出後的三年過渡期，在此期間，2008年版的證書仍然有效，讓機構擁有充足的時間調整其管理體系。