With the projected publication of ISO 9001:2015 in late 2015 and up to a three year transition period after its release, understanding the every minute detail of the draft should not be a pressing issue for most organizations at this time, but being aware of the overarching changes and beginning some planning for transition is advisable. Further releases will be made available by Cavendish Scott between now and the final release.

In the meantime a quick overview of some highlights in the ISO/DIS 9001 are worth discussing…

Annex SL

As previously discussed, ISO has adopted a common structure for future management system standards known as Annex SL. This very same framework has already been used in published standards such as ISO 27001: 2013 and ISO 22301: 2012; ISO 14001 (2015) is also being revised under this format. As such, integrating multiple management systems will become ever-more easy. Some familiarity with the new structure will need to be gained. For those clients who did not follow Cavendish Scott advice of not number documentation to the standard could be in for a bit of work

Risk

As seen in throughout the standard's development process, "risk" is taking on a more explicit role in the new standard. Concepts such as "risk-based thinking" and the addition of risk as a consideration in everything from customer focus to management review activities. The overarching statement "When planning the [QMS] the organizations shall consider the issues…and the requirements…and determine the **risks and opportunities** that need to be addressed" sums up the intent: *risks should be consider in any process of the QMS.* It should be noted that the DIS refers to risk both explicitly (i.e. "determine the risks", "address risks") and implicitly (i.e." potential consequences", "potential impact").

Plan-Do-Check-Act

After a brief absence in the CD, the management system PDCA cycle returns to the Introduction section of the DIS 9001 with some updates to the familiar model (i.e. reference to Annex SL sections and requirements). Additionally, a model representing a single process using PDCA is included, bringing in the consideration of risks associated with a given process; this can be seen as one of the many infiltrations of risk-based thinking into the standard.

Design and Development

After being significantly re-formatted in the CD (Development Process, Development Controls, and Development Transfer), requirements for Design and Development return to something more of their existing layout (Design and Development Planning, Inputs, Controls, Outputs, and Changes). Notable changes in the format include Design Review, Validation and Verification being dropped as section headers; however these requirements are included under Design and Development Controls within the DIS.

New Concepts and Changed Terminology

Products and Services – replaces "Product" in an attempt to be more all-inclusive to service based organizations.

Documented Information – replaces both "Documents" and "Records" under the intent that controls and requirements for these are similar in nature.

External Provider – replaces "supplier" in order to be more inclusive of arrangements with related organizations and outsourced processes.

Context of the Organization – new term intending to bring focus to the internal and external issues and requirements that can impact the obligations of the organization and its QMS.

"As Applicable" – caveat used in several requirements that may have previously been noted as "exclusions". The DIS does not refer to exclusions per se (and as such has no requirements related to them); however allowance is made for certain requirements to be deemed not applicable. The intent remains the same insofar as where a required can be applied, it must be applied; non-applicability is only justified when the relevant process is not carried out.

Requirements Deleted

Several requirements in the current ISO 9001:2008 remain absent in the ISO/DIS 9001 including:

- Quality Manual
- Management Representative
- Preventive Action

This is not to say that these documents, roles, processes need to be removed from an organization's QMS – if they fit your particular organization's needs, then they likely can be retained within your QMS. The intent circles back to several of the additions mentioned above including using risk-based thinking throughout the QMS (i.e. preventive action) and understanding the context/culture of the organization to plan and develop its QMS (i.e. potential need for Quality Manual and/or Representative).

While not an exhaustive review of the changes proposed in the ISO/DIS 9001, this begins to provide some scale of the potential revisions.

Generally speaking, the revision is being viewed as a significant revision. Cavendish Scott intends to provide deeper dives into the more substantial areas of change such as risk, while not making too much out of minor changes in order to provide focus and value for those tasked with understanding the planning for the coming transition.