

An ISO 9001:2015 Catch 22: Documenting Plans

By JP Russell and Denis J. Devos

ISO 9001:2015 has several requirements for organizations to plan. One example is clause 6.1.2 that requires the organization to plan actions to address risks and opportunities. Should those plans be documented? If so, must the plan be subject to the documented information controls according to clause 7.5? Should an auditor require plans to be documented and controlled?

QUESTION: Does clause 6.1.2 require plans to address risks and opportunities to be maintained as documented information? What about other plans?

RESPONSE: The answer is no; however, there is a trap auditees and auditors must avoid.

The definition of *documented information* is information required to be controlled and maintained by an organization and the medium on which it is contained (ISO 9000:2015, clause 3.8.6).

The definition uses the words controlled and maintained. This can be confusing considering the guidance for **retained** documented information and **maintained** documented information in the ISO 9001 standard. The confusion may be that the definition states documented information must be maintained, yet examples of maintained documented information in ISO 9001:2015 Annex A6 include procedures, manuals and quality plans.

All the references to documented information in ISO 9001:2015 are either **maintained or retained**, or documented information is referenced in a generic manner (determine the documented information necessary...). Only the organization can determine if they need *documented information* (required to be controlled and maintained); for example, to describe their external provider process controls.

In the sense that *documented information* must be controlled and maintained, a plan is more generic (open-ended). A plan is not defined in the ISO 9000:2015, Quality management systems – Fundamentals and vocabulary standard. A plan can be a business plan, strategic plan, project plan, scheme, process plan, or simply a piece of paper with a sequence of steps written down. Some plans are obsolete after they are published (serve a one-time purpose).

A plan is not classified as *documented information* unless the organization requires it to be written down, controlled and maintained. The catch 22 is when an organization documents their plans and an auditor expects them to be controlled and maintained as *documented information*. An auditee could be subject to plans being audited against documented information controls. Hopefully, common sense will prevail.

Another aspect of the trap that must be avoided is for auditees to not document their plans because there is no requirement to do so. As a practical concern, it would be very difficult to have a strategic plan (for example) without it being written down. It would be similarly difficult to claim to have a “plan for acting on risks and opportunities” without such a plan being written down. How would one be able to track the completion of tasks on an undocumented plan or measure their effectiveness? Again, it is hoped that common sense will prevail.

CONCLUSION:

An auditor needs to verify that planning took place. The evidence provided by the auditee may be a plan or other document available in some form or media. The catch 22 is that it does not need to be documented information and audited for document control according to clause 7.5 requirements.

It is up to the organization to determine what documented information they need to maintain. The need depends on many factors such as regulations, safety, communications, risk, complexity of operations, and so on. Once the result of planning is identified as documented information, the organization has added flexibility because many of the clause 7.5 controls are open-ended. Several requirements are qualified as “as applicable” or to “ensure appropriate” actions.

Plan what you do and do what you plan.

Note: The comments in this article are our personal comments and not that of any organization to which we belong.

Authors:

J.P. Russell is managing director of QualityWBT Center for Education. He is also an American Society for Quality (ASQ) Fellow, ASQ-certified quality auditor, member of the ASQ Z1 auditing committee, secretary of ASQ standards committee and member of the U.S. technical advisory group for International Organization for Standardization technical committees 176 (quality) and PC 302 (auditing). Russell is a recipient of the Paul Gauthier Award from the ASQ Audit Division, two ASQ testimonial awards and author of several ASQ Quality Press books about auditing, standards and quality improvement.

Denis J. Devos is a Fellow of the American Society for Quality (ASQ) and a recognized expert in the application of the ISO 9001 family of standards. He is a regular contributor to ASQ conferences on quality management and auditing. Denis Devos has been integrating risk and quality management since the publication of his “Risk is the Compass” auditing model in 2005. Devos Associates provides training and advisory services across a variety of industries.