



PERRY JOHNSON REGISTRARS, INC.



ISO 9001:2015: Knowing What to Expect to Ensure a Stress Free Audit



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Certification to ISO 9001 is an investment of not only money, but a good deal of time and effort as well. Concerns that preparations before a first-time certification audit may be inadequate, or that there may be aspects of the business being overlooked can be inherently stressful. But certification doesn't have to produce anxiety – how can organizations new to ISO 9001 approach their audits stress-free?

Before looking at strategies that might help an organization prepare to be audited, it's important to speak to the ISO 9001:2015 standard itself. ISO 9001:2015 is an interpretive document, a key fact to recognize and remember. The 2015 edition was the very first version of ISO 9001 to include an explanatory Appendix (Appendix A), and it has since become one of the few ISO standards to have a separate supplemental standard for explanatory purposes. That supplement, ISO/TS 9001:2016, was published on November 1, 2016 under the full title “Quality Management Systems – Guidelines for the Application of ISO 9001:2015.” As an officially sanctioned guidance document, it provides clause-by-clause ideas on how an organization may best fulfill the requirements of ISO 9001.

As outlined previously and as explained in ISO 9002, the interpretive nature of ISO 9001 means that none of the standard's requirements have a “perfect” method for implementation; it is up to an individual organization to determine the appropriate methodology for implementation. The auditor's role during the ISO 9001 audit is to review the chosen methodology and determine whether or not the method represents a sufficient fulfillment of the requirement.

Interestingly, in the five years ISO 9001:2015 has been in print (with the ISO 9001 standard having been in print for more than thirty), many of the same points continue to be cited in ISO 9001 audits year after year. In 2018, PJR conducted a data mining exercise to identify the five most commonly cited areas of nonconformances. From most to least common, the five areas were: Management Review Meetings, Internal Audits, Quality Objectives, Calibration/Verification of Monitoring & Measuring Resources, and External Provider Appeals.

Clause 9.3 of ISO 9001, as the most commonly-cited area for nonconformance, covers requirements for management review. The first subclause of 9.3 requires “planned intervals” for controlling the frequency and content of management review meetings. As in other requirements within ISO 9001, it is at the discretion of the organization seeking certification to set actual controls for the requirement. Some acceptable controls observed in past audits for 9.3.1 include internal schedules, procedural stipulations, and automated reminders.

Subclause 9.3.2 outlines expectations for procedural plans and discussion points within the management review, such as status of action items from previous meetings, changes in issues relevant to the QMS, trends in QMS performance, etc. While not every single management review must include these items, they are considered mandatory to include as applicable. While not mandatory, some organizations find it helpful to prepare a PowerPoint presentation or other overview of relevant content, and utilize a standardized agenda format for management review to ensure required discussion points are not missed.

Finally, subclause 9.3.3 outlines the expected outcomes of management review. Simply put, a management review is intended to be a productive meeting, highlighting decisions and actions taken based upon presented information; it is not meant to simply be a “churn of information.” Auditors must be able to confirm objective evidence of decisions made and subsequent actions taken in order to determine that pertinent information is being retained.



The second most common area for nonconformance is clause 9.2, covering internal audits. 9.2.1 covers the requirements of these audits to be regularly planned, to follow the requirements ISO 9001, and with the goal of determining whether the QMS conforms to the organization's requirements. Once more on the point of “planned intervals,” internal audits must be conducted according to a planned scheduling mechanism. This could include a calendar trigger, audit plans, database scheduling, or a combination thereof. Organizations are also permitted to conduct their internal audits in “small bites” if desired. The organization is expected to ensure that all requirements from ISO 9001:2015 are included in the internal audit process – this *does* include “auditing the audit.” Internal audits should be structured with respect to the processes that make up their QMS, not the clauses of ISO 9001:2015 itself.

The second part of this clause, 9.2.2, covers the impartial and objective selection of auditors and audit conduct to ensure appropriate corrective actions are taken and that information is retained as evidence of the audit program's implementation as well as the audit results. While ISO 9001:2015 does not specify a minimum requirement of auditor competency for internal audits, the organization is expected to determine for itself what makes an internal auditor competent. Internal auditor qualification records should likewise not consist of merely a training signoff; competency requirements must be clearly determined, per ISO 9001:2015 clause 7.2.

One key issue that frequently arises with regard to internal audits is a lack of responsiveness to internal audit nonconformances; these must be treated with the same seriousness afforded to nonconformances found in audits by PJR or in response to customer complaints. Furthermore, evidence (a.k.a. records) of the internal audit process at large are expected. The method of recording used is at an organization's discretion, but the records must be sufficiently detailed to offer confidence that the entire QMS was included.

An important factor to consider is the use of consultants. While an organization may choose to outsource their internal audit program to a consultant, the overall final responsibility for the internal audit program (from scheduling and maintenance to responding to nonconformances) belongs to the organization being certified, not the consultant. Likewise, the organization should be able to confidently speak to their internal audit process and how it is controlled, regardless of consultant use.

Quality objectives, the third most-common area to see nonconformances in, is split into two sub-clauses. First is 6.2.1, which outlines the measurability, relevance, and oversight of quality objectives (among other points). Foremost, all quality objectives must be measurable; without this aspect, it is impossible to reliably determine if an objective has truly been met. This may include variable measurement types or attribute types. Relevancy is also important; objectives must be relevant to customer satisfaction and products/services. This is a new requirement to the 2015 version of ISO 9001. Finally for 6.2.1, quality objectives are a topic that everyone in a QMS audit is expected to demonstrate knowledge and awareness of. This may be achieved by placards, meetings, or other methods – no specific methodology is mandatory.

Clause 6.2.2 mandates that an organization must determine what will be done, what resources will be required, who will be responsible, when it will be completed, and how results will be evaluated when planning how to achieve quality objectives. The key takeaway from this requirement is that it is not enough to simply have established quality objectives. Rather, an organization must track the progress made toward quality objectives and take necessary action to improve performance as necessary. A “necessary action” means an appropriate response; it may not necessarily mean a formal corrective action.

The next requirement where nonconformances are typically seen is commonly referred to as “calibration,” and falls under the primary clause 7.1.5 in ISO 9001:2015. It is divided into two sub-clauses, the first of which (7.1.5.1) emphasizes that resources for valid and reliable results must be provided, that the provided resources are suitable, and that appropriate documented information is being retained as evidence of fitness for purpose of the monitoring and measurement resources. For a majority of organizations, this will take the form of calibration or verification records for *all* measurement devices. The content of such records is influenced by the second point (suitability of resources).



The second part of the calibration clause, 7.1.5.2, determines that measuring equipment must be calibrated/verified against international or national measurement standards, identified to determine status, and safeguarded from adjustments, damage, or deterioration that may invalidate calibration status. The two most violated aspects of this requirement are the required traceability to “national or international standards” and consistent and reliable device “identification in order to determine status.” In the case of the former, the standards used will tie to the National Institute of Standards & Technology (NIST), or else the calibration will be performed by the device manufacturer. In the case of the latter aspect, it is commonly misconceived that the requirement calls for “calibration stickers” – this is not the case. So long as there is some form of device identification that permits traceability to calibration records, any approach may be acceptable.

Finally, the fifth most common area for nonconformances is external provider approvals. While in older versions of ISO 9001 a reader may have found terms such as “suppliers,” “subcontractors,” or “outside partners,” these terms were merged under the collective term “external provider” in the 2015 version of the standard. (Note that the requirement for these parties to be approved is not new; it resides in paragraph three of clause 8.4.1.)

The external provider approvals requirement outlines how organizations must determine and apply criteria for evaluating, selecting, monitoring performance of, and re-evaluating external providers based on their ability to offer processes or products/services in accordance with requirements. Additionally, the organization is required to retain documented information of these activities. The methodology for approvals must be established in advance. What that methodology is and whether there are alternatives possible is entirely at the organization's discretion. Emphasis should be placed on the requirement's call for monitoring and re-evaluation to ensure a supplier's continued suitability. Finally, organizations ought to note that the “retained documented information” requirement specifies that evaluation activities are to be “on the record” – this means that having the external provider's name on a list is insufficient evidence on its own, and does not constitute a record that evaluation was performed.

In conclusion, ISO 9001:2015 remains the world's most utilized standard, with just over 1.2 million registered organizations. Many of the items cited in nonconformances, including those discussed in this document, are completely avoidable – yet they seem to recur time and time again no matter the version of ISO 9001. We at Perry Johnson Registrars, Inc. hope that this overview of the five most common areas for nonconformances will help offer you insight and confidence as you approach your own initial ISO 9001:2015 certification audits. For more information and other resources on ISO 9001 (or other certification standards and services), visit our website at www.pjr.com or call (248) 358-3388.

