

ISO 9001:2000 - WHEN ARE WE READY?

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An effective Quality Management System (QMS) is never really “complete”, as there should always be emphasis on continuously improving the performance of the processes that make up the QMS and the products that are provided the organization. While a properly designed QMS isn’t ever going to be truly finished, it can be “ready” in terms of being an adequate, suitable and effective tool capable of having a positive impact on the operations being performed by the implementing organization.

For many organizations, this “readiness” is validated by obtaining third-party registration from an accredited ISO 9001 registrar. For organizations that new to the registration process, as the name implies, this is an activity performed by an accredited outside organization to verify that the organization has adequately documented and effectively implemented their QMS in accordance with the requirements of the ISO 9001:2000 standard.

Prior to attempting ISO 9001:2000 registration, an organization should assess their level of preparedness and degree of compliance with the ISO 9001:2000 standard. Primarily, this assessment is made through the performance of a formal, documented “internal audit” of the QMS and its related processes, performed by either qualified internal personnel or by utilizing the services of an outside contractor. The performance of an internal audit is specifically required by the ISO 9001 standard, so it must precede the registration process regardless.

For a program that is “new” – one that was recently designed, developed and implemented, I personally recommend that an additional, informal review be performed preceding the more formal internal audit, just as a means of assuring that the organization has “covered all of its bases”, so to speak (think design review). This way, an informal review determines if an organization is ready for a formal internal audit, a formal internal audit determines if an organization is ready for a third-party registration audit, and a third-party registration audit determines if an organization meets the requirements for ISO 9001:2000 registration. Whew.

The purpose of this review is not to collect objective evidence of program compliance (such as in an internal audit), but rather to ensure that the program is ready for more formal assessment. As part of such review, I would initially consider at least 10 key items:

- An adequately communicated Quality Policy
- A designated Management Representative
- A documented Quality Manual
- Documented procedures required by the standard
- Additional procedure and/or Work instructions as appropriate to the complexity of the processes being performed
- Internal training of personnel on the QMS and on the activities they are performing
- A documented Management Review
- At least one Internal audit
- Adequate historical data relating to the performance of the QMS
- Adequate analysis of process performance

There's one more key item, while not directly addressed, is implied in each above - Implementation, Implementation and Implementation. Implementation is KEY. And remember, it never happened if there's no record that it was performed.

The degree of documentation generated as a result of this activity should be left to discretion of the organization, but as this is an informal review, this could be considered technically as outside of the organization's internal audit program. Being for "informational use only", this activity wouldn't be subject to the same documentation requirements as an audit, unless this was a requirement specified within the organization's procedures. Again, this is an informal review, not a formal internal audit.

Documentation should however be generated regarding any issues that were identified during this informal assessment, through the Corrective Action or Preventative Action process established with the organization's QMS. This activity will ensure that any deficiencies are adequately addressed and also serve to demonstrate the effectiveness of these two key processes. This also provides information that can be used as part of the organization's management review.

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