International Organization for Standardization

International Accreditation Forum

Date: 13 January 2016

ISO 9001 Auditing Practices Group
Guidance on:

Adding Value

What do we mean by "adding value"?

We hear so much about the importance of "adding value" during quality management systems (QMS) audits, but what does this really mean? Is it possible to add value without compromising the integrity of the audit or providing consultancy? In principle, all audits should add value, but this is not always the case.

This document provides guidance on how an audit can add value for the different parties involved, and the various situations that are likely to be encountered in the context of second or third-party audits.

"**Value-added**" quality management systems

There are several dictionary definitions of "value", but all focus on the concept of something being *useful. "Adding value"* therefore means to make something *more useful.*

Some organizations have used the ISO 9000 series of standards to develop quality management systems that are integrated into the way they do business, and are *useful* in helping them to achieve their strategic business objectives – in other words they *add value* for the organization. Conversely, other organizations may have simply created a bureaucratic set of procedures and records that do not reflect the reality of the way the organization actually works, and simply add costs, without being useful. In other words, they do not "add value".

It is a question of approach:

A non-value-added approach asks "What procedures do we have to write to get the ISO 9000 certification?"

A "value-added" approach asks the question "How can we use our ISO 9001-based quality management system to help us to improve our business?"

How to add value during the audit process?

How can we ensure that an audit is **useful** to an organization in maintaining and improving its QMS?(We should recognize, however, that there may be other perspectives that need to be taken into consideration.)

In order to "add value", a third-party audit should be useful:
- to the certified organization
  - by providing information to top management regarding the organization's ability to meet strategic objectives
  - by identifying problems which, if resolved, will enhance the organization's performance.
  - by identifying improvement opportunities and possible areas of risk
- to the organization's customers by enhancing the organization's ability to provide conforming product
- to the certification body, by improving the credibility of the third party certification process.

The approach to "adding value" is likely to be a function of the level of maturity of the organization's quality culture and the maturity of its QMS, with respect to the requirements of ISO 9001.

By referring to Figure 1, we can conceptually separate organizations into four different zones, as follows:
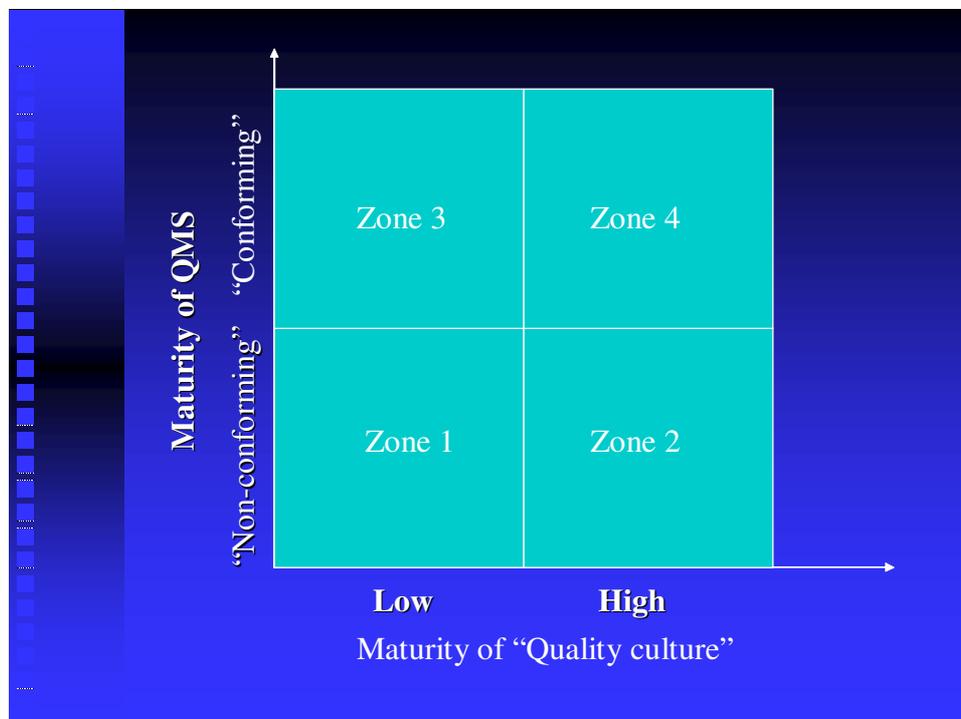
Zone 1: (Low maturity of "quality culture"; immature QMS, not conforming to ISO 9001)
Zone 2: (Mature "quality culture"; immature QMS, not conforming to ISO 9001)
Zone 3: (Low maturity of "quality culture"; mature QMS, conforming to ISO 9001)

Zone 4: (Mature "quality culture"; mature QMS, conforming to ISO 9001)

It is important to note that in this context:

"**Quality culture**" refers to the degree of awareness, commitment, collective attitude and behaviour of the organization with regard to quality.

"**Conformity to ISO 9001**" relates to the maturity of the organization's QMS, and the extent to which it meets the requirements of ISO 9001. (It is recognized that specific minor nonconformities might be detected even in organizations that show an overall high degree of maturity and conformity to ISO 9001.)

Zone 1: (Low maturity of "quality culture"; immature QMS, not conforming to ISO 9001)

For an organization that has little or no "quality culture" and a QMS that does not conform to ISO 9001, the expectation of how an audit might add value could mean that the organization would like to receive advice on "*how to*" implement the quality management system and/or resolve any non-conformities raised.

Here the auditor has to take great care, because in a third party audit such advice would certainly generate a conflict of interest, and would contravene the requirements in ISO/IEC 17021 for the accreditation of certification bodies. What the auditor *can* do, however, is ensure that whenever non-conformities are encountered, the auditee has a clear understanding of *what* the standard requires, and *why* the non-conformity is being raised. If the organization can recognize that resolving these nonconformities, will lead to improved performance, then it is more likely to believe in and commit to the certification process. It is important, however, that all identified non-conformities *are* reported, so that the organization clearly understands *what* needs to be done in order to meet the requirements of ISO 9001.

While some organizations might not be totally satisfied with an audit outcome that does not result in certification, the organization's customers (who receive the organization's products) will certainly consider this to have been a "valuable" audit from their perspective. From the perspective of the certification body, failing to report all detected nonconformities and/or providing guidance on *how to* implement the quality management system, adds no value to the credibility of the auditing profession or the certification process.

We must recognize that the above discussion relates mainly to third party (certification) audits. There is no reason why a second party (supplier evaluation) audit should not "add value" by providing guidance to the organization on how to implement its quality management system. Indeed, under these circumstances, such guidance (if it is well-founded), would undoubtedly be useful for both the organization and its customer.

Zone 2: (Mature "quality culture"; immature QMS, not conforming to ISO 9001)

For an organization that has a mature "quality culture", but an immature QMS that does not conform to the ISO 9001 requirements, the basic expectation of how an audit might add value will probably be similar to that of Zone 1. In addition, however, the organization is likely to have a much higher expectation of the auditor.

In order to be able to add value, the auditor has to understand the way in which the organization's existing practices meet the requirements of ISO 9001. In other words, understand the organization's processes in the context of ISO 9001, and not, for example,

insist that the organization redefine its processes and documentation to align to the clause structure of the standard.

The organization might, for example, base its management system on business excellence models, or total quality management tools such as Hoshin Kanri (Management by Policy), Quality Function Deployment, Failure Mode and Effect Analysis, "Six-sigma" methodology, 5S programmes, Systematic Problem Solving, Quality Circles and others. In order to add value during the audit process, the auditor should, at a minimum, be aware of the organization's methodologies, and be able to see to what extent they are effective in meeting the requirements of ISO 9001 for that particular organization.

It is also important that the auditor not be "intimidated" by the organization's apparent high degree of sophistication. While the organization may be using these tools as part of an overall total quality philosophy, there might still be gaps in the way the tools are being employed. Therefore, the auditor must be able to identify any systematic problems and raise the appropriate non-conformities. In these situations, the auditor might be accused of being pedantic or even bureaucratic, so it is important to be able to demonstrate the relevance of the non-conformities that are being raised.

Zone 3: (Low maturity of "quality culture"; mature QMS, conforming to ISO 9001)

An organization that has been certified to one of the ISO 9000 series of standards for a significant period of time might be able to demonstrate a high level of conformity to ISO 9001, but at the same time not have truly implemented a "quality culture" throughout the organization. Typically, the QMS might have been implemented under pressure from customers, and built around the requirements of the standard, rather than on the organization's own needs and expectations. As a result, the QMS, may be operating in parallel with the way the organization carries out its routine operations, generating redundancy and inefficiency.

In order to add value in these circumstances, the primary objective of the auditor should be to act as a catalyst for the organization to build on its ISO 9000-based quality management system, and to integrate the system into its day-to-day operations. While the third party certification auditor cannot provide recommendations on how to meet the requirements of ISO 9001, it is acceptable and indeed good practice to **encourage** and **stimulate** (but not **require!**) the organization to go **beyond** the requirements of the standard. The questions the auditor asks (and the way he or she asks those questions) can provide valuable insights for the organization into how the QMS could become more efficient and **useful**. Identification of "Opportunities for Improvement" by the auditor should include ways in which the effectiveness of the QMS might be enhanced, but could also address opportunities for improved **efficiency**.

Zone 4: (Mature "quality culture"; mature QMS, conforming to ISO 9001)

For an organization that has a mature "quality culture", and has been certified to one of the ISO 9000 series of standards for a significant period of time, the expectation of how an audit might add value will be the most challenging for an auditor. A common complaint among this kind of organization is that the "routine surveillance visits" by the auditor may be superfluous, and do little to add value in the organization's eyes.

In these cases, top management becomes an important customer of the certification process. It is therefore important for the auditor to have a clear understanding of the

organization's strategic objectives, and to be able to put the QMS audit within that context. The auditor needs to dedicate time for detailed discussions with top management, to define their expectations for the QMS, and to incorporate these expectations into the audit criteria.

Some tips for the auditor on how to add value

1) **Audit planning**:

   a. Understand the auditee's expectations/corporate culture
   b. Any specific concerns to be addressed (output from previous audits)?
   c. Risk analysis of industry sector / specific to organization.
   d. Pre-evaluation of statutory/regulatory requirements
   e. Appropriate audit team selection to achieve audit objectives
   f. Adequate time allocation

2) **Audit technique:**

   a. Focus more on the process, and less on procedures. *Some* documented procedures, work instructions, check-lists etc. may be necessary in order for the organization to plan and control its processes, but the driving force should be process performance.

   b. Focus more on results and less on records. In a similar fashion, *some* records may be necessary in order for the organization to provide objective evidence that its processes are effective (generating the planned results) but in order to add value, the auditor should be aware of and give credit for other forms of evidence.

   c. Remember the 7 Quality Management Principles

   d. Use the "Plan-Do-Check-Act" approach to evaluate the organization's process effectiveness.
      i. Has the process been planned?
      ii. Is it being carried out according to plan?
      iii. Are the planned results being achieved?
      iv. Are opportunities for improvement being identified and implemented?
         — By correcting non-conformities
         — By identifying root causes of problems and implementing corrective action
         — By identifying trends, and the need for preventive action
         — By innovation

   e. Adopt a "holistic" approach to evidence gathering throughout the audit, instead of focusing on individual clauses of ISO 9001.

3) **Analysis and decision**

   a. Put the findings into perspective (Risk based thinking / "common sense").

   b. Relate findings to the effect on the organization's ability to provide conforming product (see ISO 9001 clause 1).

4) Report and follow-up

    a. Sensible reporting of audit findings
        i. Different approaches may be required depending on:
- the organization's maturity (Zones 1, 2, 3 and 4)
- the level of confidence in the organization's QMS
- the risks involved
- the auditee's attitude and commitment to the audit process
  - Proactive
  - Reactive

        ii. Ensure that any cultural aspects are taken into consideration
        iii. Emphasize positive findings as appropriate
        iv. Will the solution proposed by the organization in response to negative findings be *useful*?

    b. Reports should be objective and focused on the right "audience". (Top management will probably have expectations that are different from those of the management representative).

For further information on the ISO 9001 Auditing Practices Group, please refer to the paper: *Introduction to the ISO 9001 Auditing Practices Group*

Feedback from users will be used by the *ISO 9001 Auditing Practices Group* to determine whether additional guidance documents should be developed, or if these current ones should be revised.

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