

# Quality Partner Newsletter

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### Welcome to the second edition of the Quality Partner newsletter

The newsletter is designed to keep you up to date with developments in the field of Management Systems. Future editions will also include articles on Total Productive Maintenance (TPM)

This issue focuses on:

- ISO9001: 2015 and the requirement “Strategic Direction and Organizational Context
- ISO/TS16949 revision update
- ISO/TS16949 sanctioned interpretation update
- ISO/TS16949 customer specific requirements

Any requests for topics in future issues can be sent to: [enquiries@qualitypartner.co.uk](mailto:enquiries@qualitypartner.co.uk)

### Quality Partner Activities

Since it was founded in August 2015, Quality Partner has provided practical training and support related to ISO9001: 2015, ISO/TS16949 and the associated core tools to certification bodies and organization personnel in UK, Malaysia and Thailand.

All Quality Partner training is based on a “learn by doing” approach, with lots of delegate exercises, case studies and ample time for open discussion.

For more information on all the courses available visit: [www.qualitypartner.co.uk](http://www.qualitypartner.co.uk)

### ISO9001: 2015 Strategic Direction and Organizational Context

ISO9001: 2015, issued in September 2015, adds requirements related to an organizations strategic direction and how this relates to context. So, what do these requirements really mean and what evidence will organizations have to provide auditors to meet the requirements?

For organization’s to be in business, they will certainly have plans for the future direction, but these will need to be reviewed, documented and incorporated into the Quality Management System.

The following article studies the requirements in more detail and gives practical examples on achieving compliance:

## ISO9001: 2015: Strategic Direction and Organizational Context

ISO9001: 2015 adds some interesting new requirements to challenge the Top Management in an organization.

Clause 4.1 states:

“The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.

The organization shall monitor and review information about these external and internal issues”  
The notes (for guidance only) encourage an organization to consider external and internal factors in understanding context.

### External factors may include:

- **Legal:** Are there any legal or regulatory requirements to consider?
- **Technological:** What is the current technology and is it changing? (e.g. Move to electric cars, non-metallic materials etc.)
- **Competitive:** Increasing competition?
- **Market:** Current market, future markets?
- **Cultural:** People migration, diversity?
- **Social:** Higher retirement age, changing working hours?
- **Economic environments:** Whether international, national, regional or local
- **Political situation:** Changing government, growth or recession?

### Internal factors may include:

- **Values:** What are the company values?
- **Culture:** What is the company culture?
- **Knowledge:** What is the level of knowledge required in the organization, any knowledge gaps through changing technology etc.?
- **Performance of the organization:** Is the company in a state of growth or markets declining, how has performance been against key performance indicators etc.?

Once these factors are understood the strategic direction must be established/reviewed. ISO9001: 2015 does not mandate any specific method of doing this, but could include using any combination of techniques which may include SWOT analysis, brainstorming, benchmarking or use of an existing business planning process.

An example of a SWOT analysis is shown below. This could be used as evidence in an audit, as it would relate to both external and internal context.

The output of the SWOT analysis could be used to develop/change the strategic direction of the organization. Again ISO9001: 2015 is not specific on the format this should take, but typically could be a business plan linked to the vision/mission of the organization.

<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>• Strong financial position, no debt</li> <li>• Committed workforce with average of 18 years service</li> <li>• Improved communication with customer by opening regional office</li> <li>• Committed investors</li> </ul>	<p><b>Weaknesses</b></p> <ul style="list-style-type: none"> <li>• Old presses, reoccurring breakdowns causing customer disruptions</li> <li>• Lack of investment in infrastructure, building in poor condition</li> <li>• Pressings limited to maximum 100 tonne machines</li> <li>• Limited experience with materials other than mild steel</li> <li>• Very dependant on one customer</li> <li>• Very dependant on one raw material supplier in Mexico</li> <li>• Lack of a defined process for succession planning</li> </ul>
<p><b>Opportunities</b></p> <ul style="list-style-type: none"> <li>• Opportunity to grow global customer base.</li> <li>• Customer opening a manufacturing facility in China in 2017</li> <li>• Opportunity to make acquisitions from other struggling pressing companies</li> <li>• Opportunity to grow automotive business with GM due to good reputation from press tooling</li> </ul>	<p><b>Threats</b></p> <ul style="list-style-type: none"> <li>• Staff turnover high, recruitment difficult</li> <li>• Deteriorating relationship with union</li> <li>• Government restrictions on import of raw materials from Mexico</li> <li>• Slowdown in growth in White Goods market in USA</li> <li>• Customers potentially moving to non-metallic panels</li> <li>• Deteriorating security situation in Mexico threatens supply of raw materials</li> <li>• Strength of US dollar</li> <li>• Hurricane frequency increasing</li> </ul>

Once the strategic direction is established, Top Management shall (clause 5.1.1):

“b) Ensure that the **quality policy** and **quality objectives** are established for the quality management system and are compatible with the **context and strategic direction of the organization**.

When establishing/reviewing the **quality policy** Top Management shall ensure it is appropriate to the purpose and context of the organization and supports its strategic direction;”

Many ISO9001 organizations make bold statements in their current Quality Policies, such as “delight customer”, “world class”, “motivate employees” etc., now auditors will check that these link to the strategic direction and context of the organization.

Once the policy is established, ISO9001: 2015, clause 6.2.1 requires:

“The organization shall establish **quality objectives** at relevant functions, levels and processes needed for the quality management system. The **quality objectives** shall:

a) be consistent with the **quality policy**;

Once the objectives are established and deployed, Top Management then have to undertake management reviews of the Quality Management System at planned intervals to ensure its continued suitability, adequacy and effectiveness **and** its alignment with the strategic direction of the organization.

The management review needs to consider changes in internal or external factors that may result in changes in the strategic direction, it should be an ongoing, dynamic process.

In summary, organizations need to apply the PDCA approach as shown below. While ISO/TS16949 certified organizations will already be familiar with this approach and the audit focus on the effectiveness of the Top Management processes, for many ISO9001: 2008 certified organizations it will be a significant change. While many of the things mentioned above will be already be addressed within an organization, often this is not within the framework of the Quality Management System.

It will also be a significant challenge for auditors, both internally within the organization and third party certification bodies, to develop the competency to audit the Top Management processes for effective implementation.



Below are some questions that could be asked in verifying compliance with the above requirements:

- Is the organization's strategic direction defined and aligned with external and internal factors?
- Is the Quality Policy aligned with the Strategic Direction?
- Does the Quality Policy provide the framework for the setting of Quality Objectives?
- Are the Quality Objectives measurable and take into account customer and interested party requirements?
- Are the Quality Objectives effectively deployed to all functions and levels in the organization?
- How is performance against the Quality Objectives monitored?
- Are effective actions taken when the Quality Objectives are not met?
- How is performance monitored as part of the Management Review process?
- How is the strategic direction reviewed/updates when there are changes in internal/external factors?

For help in understanding the ISO9001: 2015 requirements, or training Top Management teams and Internal Auditors contact Quality Partner at [enquiries@qualitypartner.co.uk](mailto:enquiries@qualitypartner.co.uk) or by phone at +44(0)7341 845 930

## ISO/TS16949 Update

The revision process for ISO/TS16949 is underway!

The revised ISO/TS16949 specification will be formatted using the requirements of ISO9001: 2015 as the base requirements with additional harmonized automotive requirements. It is anticipated that the revised specification will be issued in September 2016 and it is likely organizations will be given 2 years to make the transition to the revised version.

To keep interested parties up to date with the proposed changes IATF have added a "subscribe to our mailing list" feature where subscribers will be kept up to date with progress of the revision. To subscribe to updates visit [www.iatfglobaloversight.org](http://www.iatfglobaloversight.org)

### **ISO/TS16949 Sanctioned Interpretations**

In October the one and only ISO/TS16949 sanctioned interpretation was amended!

Under the requirement 7.4.1.2 organizations are required to develop their suppliers, with a first step being supplier certification to ISO9001, with a goal of compliance to ISO/TS16949.

However in some countries ISO9001 certificates are issued by certification bodies with no internationally recognized accreditation and hence their validity and worth are questionable.

The sanctioned interpretation now requires ISO/TS16949 certified organizations to verify that suppliers' ISO9001 certificates are issued by a valid IAF MLA recognized certification body bearing an accreditation body mark whose scope includes certification to ISO/IEC17021. Help in verifying this can be found at <http://www.iaf.nu> where a list of IAT MLA accreditation bodies can be downloaded.

If in undertaking the review it is found that a supplier certificate does not meet the above requirements, the ISO/TS16949 certified organization has two choices:

1. Ask the supplier to transfer their certification to a certification body whose accreditation meets the IAF MLA requirements and complete this transfer by 31st December 2017 or
2. Undertake second party audits of the relevant supplier in line with the requirements and frequency defined in the sanctioned interpretation.

### **ISO/TS16949 Customer Specific Requirements**

Whereas ISO/TS16949 went some way in harmonizing automotive quality system requirements, individual vehicle manufacturers and suppliers also impose their own requirements and publish them as "Customer Specific Requirements"

Hopefully some of the common customer specific requirements will be harmonized into the revised ISO/TS16949, but I am sure many will remain.

In November 2015, the revised edition of the Ford Motor Company customer specific requirements became effective.

The changes include, but not limited to:

- Records, including process control and inspection records, and reaction plans to be retained in a recoverable format for a minimum of 2 years.
- For variable data, pass/fail recording not acceptable, must record specific values.
- People involved in capacity planning must have capacity analysis training and review this annually, and retake training if requirements change.
- Organizations must utilize the AIAG Service PPAP manual for service parts.
- First tier suppliers must ensure all tiers of suppliers are assessed to applicable Ford Manufacturing process standards (e.g. CQI standards).
- Each ISO/TS16949 third party audit will verify that certified organizations have an effective process for identifying, reviewing and implementing relevant customer specific requirements, so do not get caught out!