Quality Partner Newsletter

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Welcome to this first 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 first issue focuses on:

- An introduction to Quality Partner

- ISO9001: 2015 and focus on risk based thinking

- ISO/TS16949 update including key customer specific requirements

- MMOG-LE

- Minimum requirements for sub-tier suppliers

- GM BIQS requirements

Introduction to Quality Partner

Established in August 2015 by Paul Hardiman, Quality Partner is a network of global experts in Management Systems and Total Productive Maintenance (TPM).

All the partners have been hand- picked based on proven training and consultancy experience, as well as having positive, constructive approach.

Training in perceived "boring" subjects such as ISO/TS16949 and the associated core tools requires trainers who can make training fun as well as being a learning experience.

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

ISO9001: 2015 is here!

After over three years in development September will see the issue of ISO9001: 2015, along with the fundamental and vocabulary standard ISO9000.

Since the concept, the revision has focused on "Risk Based Thinking".

For organization's to be in business, they will certainly have some processes and systems in place to manage risk, these will need to be reviewed and incorporated into the Management System.

For examples many companies have contingency plans or disaster recovery plans, but are often not subject to formal review and are out of date. See more on the next pages.......

Approaches to Risk Based Thinking

What is risk?

The definition in ISO9000: 2015 is effect on uncertainty. The notes explaining this state that the effect can be a positive (opportunity) or negative (threat). Uncertainty can be defined as the deficiency of information, related to or understanding of an event, the consequence or likelihood.

The standard stresses that risk need not only be though about as negative, but can bring positive effects. Let's think about a simple every day situation, crossing a road to buy lunch. This can give an opportunity, to get the lunch we want, but in undertaking the task this carries some possible risks. Before we can consider risk we need to think about the "boundaries" of the situation, i.e. where we are crossing.

By understanding the boundaries we can now use appropriate techniques to identify and rank the risks before we make the decision on whether to cross. Maybe we can buy lunch without crossing but maybe not as good!

Now let's consider this within the context of a quality management system. The scope and boundaries of the quality management system need to be defined and understood before we can consider risks and opportunities. For example does the scope include design and/or any remote support functions (sales offices, home based workers etc?).

Once established we can now consider risks and opportunities. Firstly it may be worth reviewing what is already in place, even if not fully included in the scope of the current quality management system. For example many organizations will already have a disaster recovery/contingency plan, may already do feasibility review for assessing new business opportunities and use either design or process FMEA.
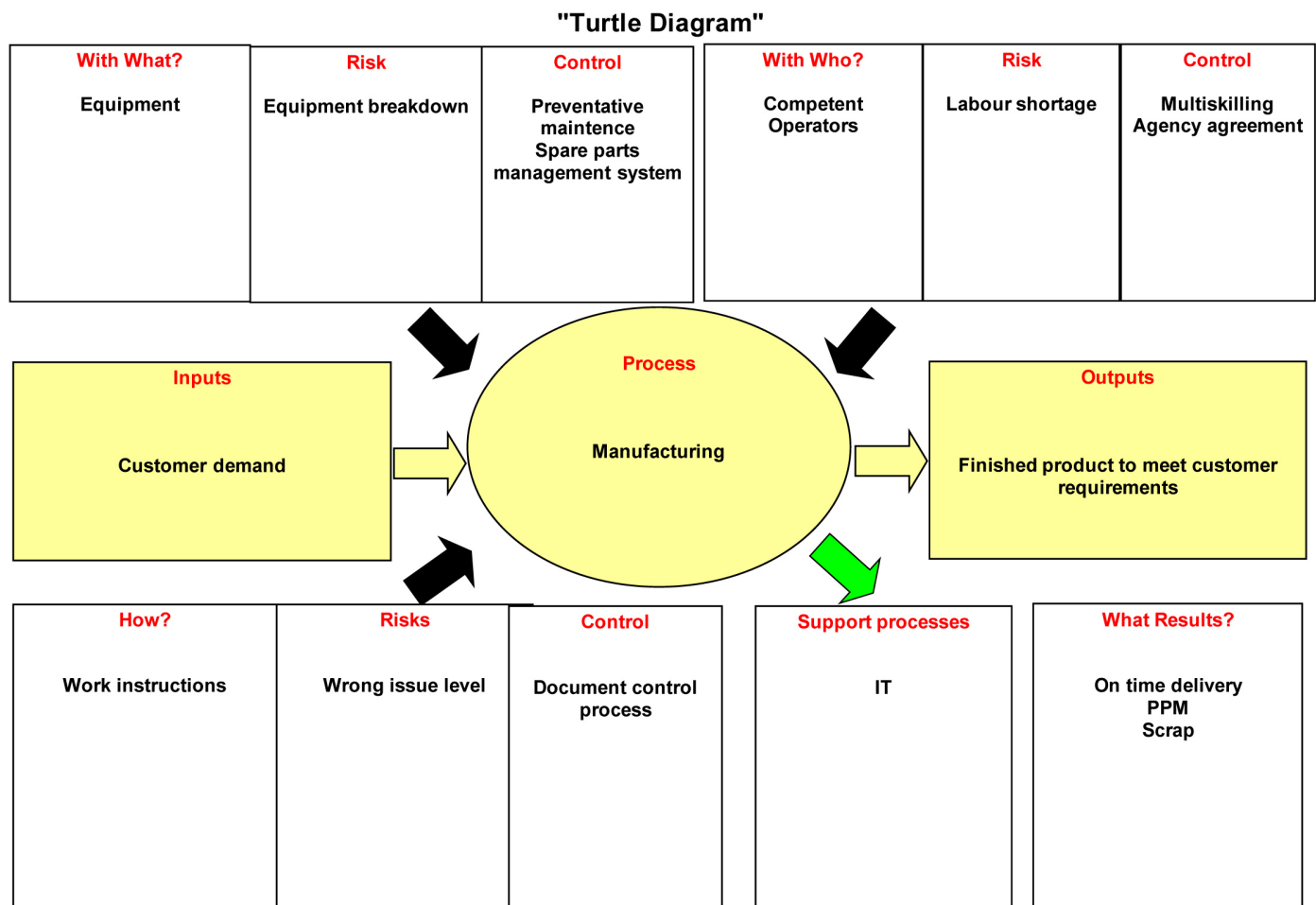
Then ISO9001: 2015 requires consideration of risk and opportunities in all quality management system processes, not just manufacturing. This needs to be led by Top Management in the organization as stated in the requirement 5.1 Leadership and commitment "Top Management shall demonstrate leadership and commitment with respect to the quality management system by promoting the use of the process approach and risk based thinking".

Risk identification techniques

ISO9001: 2105 does not give solutions, only requirements. It is the responsibility of organizations to identify and use appropriate risk identification techniques. This could include Brainstorming, Questionnaires, Industry Benchmarks, Scenario analysis, Risk assessment workshops, FMEA, Fault tree analysis, Contingency planning, Feasibility review or the "Turtle diagram".

The technique used may vary depending on the process being evaluated. In the automotive supply chain, the use of the "Turtle diagram" has been promoted to analyze a process and is often used in auditing a process. However in many cases the "Turtle diagram" only considers current controls, not all aspects of risk and opportunity.

One solution is to modify the turtle diagram to better consider the risk and controls.
A simple example is shown below (not complete, for example purpose only).

"Turtle Diagram"

With What?	Risk	Control	With Who?	Risk	Control
Equipment	Equipment breakdown	Preventative maintence Spare parts management system	Competent Operators	Labour shortage	Multiskilling Agency agreement

Inputs	Process	Outputs
Customer demand	Manufacturing	Finished product to meet customer requirements

How?	Risks	Control	Support processes	What Results?
Work instructions	Wrong issue level	Document control process	IT	On time delivery PPM Scrap

Once all the risks and current controls have been identified, the risks then need to be ranked to identify areas of process strengths (these strengths could be used as an opportunity to improve other processes) or weaknesses, where risks could be reduced, mitigated, or eliminated by I making changes/Improvement to the process.

Risk ranking

Again ISO9001: 2015 does not mandate any specific risk ranking method. Many companies will be familiar with FMEA, but this is a very time consuming and labour intensive process and may not be practical to use to identify and rank risk in all processes.

Other simplified techniques can be used such as the example below, which considers the probability of an event occurring and then the severity/impact if the event occurs. This could be based on a simple one to five ranking for each, meaning the minimum risk is one and maximum twenty five.

The trigger point for action can then be defined by the organization. For example the organization may decide to focus first on the risks in the red zone, then the yellow, with Management making the decision not to take any action with the risks shown in the green zone.

An ongoing process

Understanding risks and opportunities is not a one off event. Things change. Supported by management, process owners need to consider risk of change before deciding on whether to make the change/making the change.

For example in considering taking on new business, all aspects of risk need to be considered. Whereas in some organizations feasibility review considers technical and product risks, it often does not fully review the customer, business or terms and conditions risks.

Summary

This article only focuses on one aspect of the revised ISO9001 standard, Risk based thinking. There are also other changes that need to be considered which will be covered in future newsletters.

The key point is do not panic! Organizations have three years from the time of issue of the standard to make the transition.

A suggested transition plan is shown below:

- Educate management and process owners in the changes defined in ISO9001: 2015
- Process owners review what is currently in place and identify gaps
- Management and process owners decide on an appropriate risk identification and ranking techniques and train people in the techniques
- Management and process owners implement the necessary changes
- Train internal auditors in the concept of "Risk Based Thinking", review audit process and audit for the system of compliance and effectiveness
- Incorporate Risk Based Thinking into the management review process to verify ongoing suitability of the systems

Quality Partner can help you make a successful and value added transition to ISO9001: 2015. The full range of services available can be found at www.qualitypartner.co.uk or by contacting Paul Hardiman on +44 (0)7341 845930.

ISO/TS16949 Update

The IATF has completed a stakeholder survey for suggestions related to content changes to the revised ISO/TS16949 standard. The established work team is now compiling the survey responses and preparing for the build phase of the revision process.

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 late 2016 and organizations will be given 2 years to make the transition to the revised version.

To keep up to date with the proposed changes visit www.iatfglobaloversight.org

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".

Customer specific requirements are defined as interpretations of or additions to ISO/TS16949 (Customers cannot take away or exclude requirements).

This remains a major problem with the scheme, with suppliers struggling to locate the requirements and whether they have been updated. Whereas some of the IATF member requirements are available at www.iatfglobaloversight.org many other OEM and supplier requirements are not available there.

One solution is to visit www.customerspecifics.com shown below:

The site enables suppliers and certification body auditors, once they have registered (free of charge), to search for customer specific requirements, not just related to the automotive industry but covering many industry sectors. The site relies on suppliers and auditors to upload any updated versions they are aware of. While the information it is not fool-proofed (i.e. is the information posted the latest), it offers one of the best solutions available.

What are some of the key changes in ISO/TS16949 Customer Specific requirements?

MMOG-LE 4th edition

Materials Management Operations Guidelines-Logistics Evaluation (MMOG-LE) has been a customer specific requirement for many vehicle manufacturers and suppliers for a long time.

In 2014 the authors, Odette in Europe and AIAG in North America, issued MMOG-LE 4th edition. Like the third edition, MMOG-LE, based on 6 chapters, is recognized as a world class best practice self-assessment tool.

However in many organizations MMOG-LE has been a "tick box exercise" to achieve the desired result to satisfy the customer, e.g. an A rating.

With the issue of the 4th edition, vehicle manufacturers are using it as an opportunity to revisit the purpose of MMOG-LE and its use as a continuous improvement tool.
Several vehicle manufacturers are not only reviewing supplier submission results for the quality of evidence provided to support compliance but also comparing assessment results with supplier performance, especially delivery.

It is likely that any supplier providing a poor quality submissions, or giving their customer delivery issues will come under extra scrutiny and may even be subjected to a customer audit.

If you think you organizations previous submission falls in the "tick box" category, but want to use the self-assessment tool to drive continual improvement in supply chain management processes Quality Partner can help you. Services provided include MMOG-LE training or an independent assessment service.
For more details visit www.qualitypartner.co.uk

Minimum automotive quality system requirements for sub-tier suppliers

The above document is referred to in the Ford and Chrysler customer specific requirements. The document, available at www.iatfglobaloversight.org (found under the heading Ford Customer Specific Requirements) defines some of the key requirements that can be audited when undertaking an audit of a sub-tier supplier that only has certification to ISO9001.

While the document may not be mandated by your customers, it provides a useful document to help in your organization supplier development process, especially in undertaking second party audits of suppliers.

The document covers requirements for:

1. Control Plans
2. Process Approach
3. Performance
4. Internal Auditing
5. Control Of Non-Conforming Product
6. Part Approval
7. Management Responsibility

GM Built in Quality Supply based (BIQS) audit requirements

If you are a supplier to GM you should be aware that their customer specific requirements changed in May 2015 and became effective in July 2015. One of the changes was to add reference to BIQS (previously known as QSB).

The requirements state: "4.1.17 thru 4.1.29 are additional GM Customer Specific Requirements and essential GM Built In Quality Supply based (BIQS) audit requirements. It is important that there is full implementation of these clauses in order to demonstrate compliance to ISO/TS16949 and certification to BIQS".

Each of the clauses 4.1.17 to 4.1.29 has defined requirements and then gives direction on what auditors should "look for" and "look at" to verify compliance with the requirements.

If your organization needs support in understanding or implementing and of the ISO/TS16949 customer specific requirements visit www.qualitypartner.co.uk or contact paul.hardiman@qualitypartner.co.uk

Feedback and comments

If you have any comments on the contents of this newsletter, or would like to supplest topics for future editions contact Paul Hardiman at paul.hardiman@qualitypartner.co.uk or call on +44 (0)7341 845930.