Quality Partner Newsletter

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Welcome to the third edition of the Quality Partner newsletter.

The newsletter is designed to keep you up to date with developments in Management Systems and Total Productive Maintenance (TPM).

This issue focuses on:

- If we effectively implement a Quality Management System and TPM why do we still get defects?
- Ask the expert: Top Management committed to the Quality Management System, what evidence will an auditor look for?
- When to start the transition to ISO9001: 2015/ ISO/ TS16949:2015?

Any requests for topics in future issues can be sent to: enquiries@qualitypartner.co.uk

Quality Partner Activities

Wishing you all a very happy and successful 2016.

2016 will be an interesting year. After the issue of ISO9001: 2015 in September 2015, 2016 will see the issue of a revised ISO/TS16949, which will incorporate the ISO9001: 2015 standard.

ISO9001: 2015, as well as being completely changed in structure, incorporates the concept of "Risk Based Thinking".

On the 9-10th February 2016, in Birmingham, UK, Quality Partner will deliver a two day course "A practical approach to risk based thinking"

To book a place(s) visit: www.qualitypartner.co.uk

With a Quality Management System and TPM why do we still not achieve zero defects?

In this issue we focus on product quality and zero defects, one of the zeroes of Total Productive Maintenance (TPM) (the other two being zero accidents and zero breakdowns).

Is this achievable, not for just customer related issues, but internal defects?

If we can achieve or implement effective control and monitor processes, and control the man, material, method and machine (4M) then it should be an achievable goal.

The article focuses on the Quality Management System requirements related to this and some of tools in the Quality Maintenance Pillar of TPM that can support zero defects.

With a Quality Management System and TPM why do we still not achieve zero defects?

Since the issue of ISO9001: 2000 Quality Management Systems, including the automotive variant ISO/TS16949, have focused on the “Process Approach”.

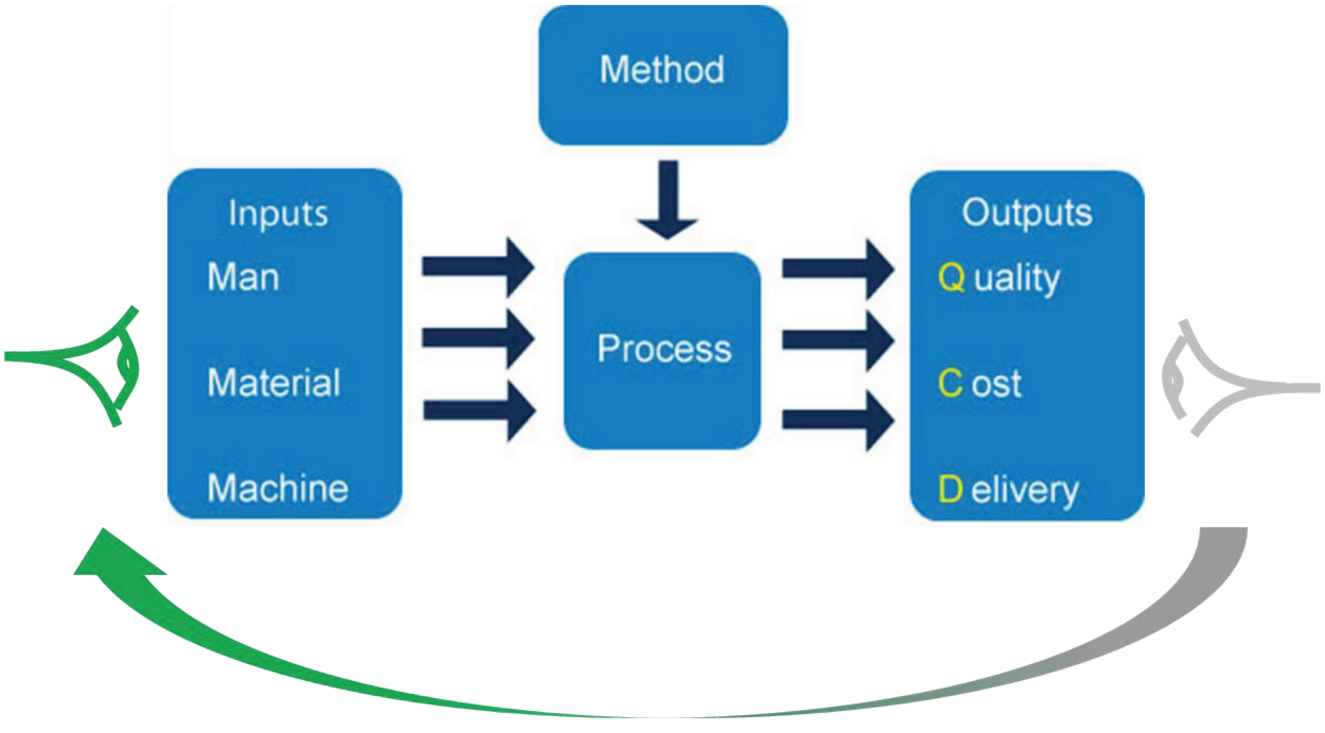
The aim of this was to ensure a Quality Management System was not something written around the clauses of the standard, but structured around an organizations business processes.

ISO9001: 2015 is no different, the process approach is still embedded as a core principle.

Requirement 4.4.1 states “The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard. The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall:

a) determine the inputs required and the outputs expected from these processes
b) determine the sequence and interaction of these processes
c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes
d) determine the resources needed for these processes and ensure their availability
e) assign the responsibilities and authorities for these processes
f) address the risks and opportunities as determined in accordance with the requirements of 6.1
g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results
h) improve the processes and the quality management system.”

So let’s look at a process and the relationship with the 4M (Man, Material, Machine and Method) condition:



We have to believe that, if we effectively control the 4M then we should be able to achieve zero defects.

ISO9001: 2015 has specific requirements related to control of 4M including:

Man: 7.2 Competence “Ensuring that personnel are competent on the basis of appropriate education, training or experience”

Material: 8.4 Control of externally provided processes, products and services “The organization shall ensure that externally provided processes, products or services conform to requirements”

Method: 8.5.1 Control of production and service provision “The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable:

The availability of documented information that defines:

1. The characteristics of the products to be produced, the services to be provided, or the activities
2. The results to be achieved”

Machine: Again this links to 8.5.1 Control of production and service provision “The use of suitable infrastructure and environment for operation of processes”

I believe control of “Machine” is a weakness in ISO9001. The standard writers have a difficult task. They are trying to write Management System requirements to cover all industry sectors, manufacturing, process and services industries, so they cannot be too specific on control and maintenance of machines and equipment.

That is why sector based standards add significant additional requirements related to preventive and predictive maintenance. ISO/TS16949 states:

“The organization shall identify key process equipment and provide resources for machine/equipment maintenance and develop an effective planned total preventive maintenance system”

Some organizations also implement TPM programs to better manage and control equipment.

So let’s look at tools that can help identify the source of defects and help in defect reduction in the journey towards zero defects.

In the Japan Institute of Plant Maintenance (JIPM) TPM model, the Quality Maintenance pillar uses the tools of QA, QX and QM matrix.

QA matrix

The QA matrix is a tool that looks at the relationship between defects and the steps in the manufacturing process to make a product. The matrix can be used for internal or external defects, or both combined together. If the number of defects is known, but no hard data is available on where the defect occurred, this can be estimated by the team developing the matrix, either as a number, or % contribution. A simple example is shown below for an organization making painted components:

	Cutting	Bending	Drilling	Painting	Number of defective products
Short length	200	50			250
Wrong angle		100			100
Surface damage	120	60	90	240	510
Orange peel				360	360

Now we need to think about the defects and the 4M condition. Again, while there may not be hard data on which of the 4M had the biggest contribution to the defect, the team will often have an idea on why the defect occurred.

Defects	Processes																Total occurrences by defect mode
	Cutting				Bending				Drilling				Painting				
	Man	Mat	Mth	Mc	Man	Mat	Mth	Mc	Man	Mat	Mth	Mc	Man	Mat	Mth	Mc	
Short length	200						50										250
Wrong angle					50			50									100
Surface damage			120		30		30				90		120		60	60	510
Orange peel														60		300	360

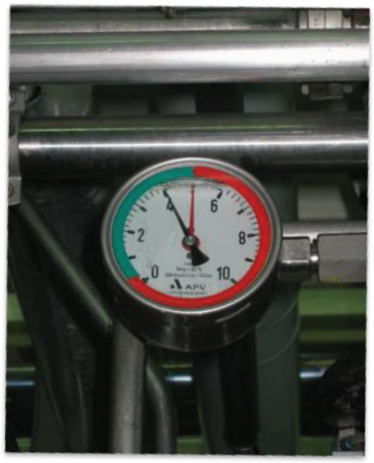
For defects likely to be caused by Man, Material or Method standard problem solving tools can be used to find the root cause and eliminate the problems. Which problems to address first can be based on “Risk Based Thinking” For example which defect has the greatest impact on the customer or the organization.

Where it is identified that the Machine is the greatest possible contributor to the defect JIPM recommend use of a QX matrix.

QX Matrix
The QM Matrix focuses on the machine parameters and settings.

The first task is to review what process parameter(s) are key to avoid the defect. In many cases the process parameter (s) will be specified, in a work/ setting instruction and in ISO/TS16949 the control plan.

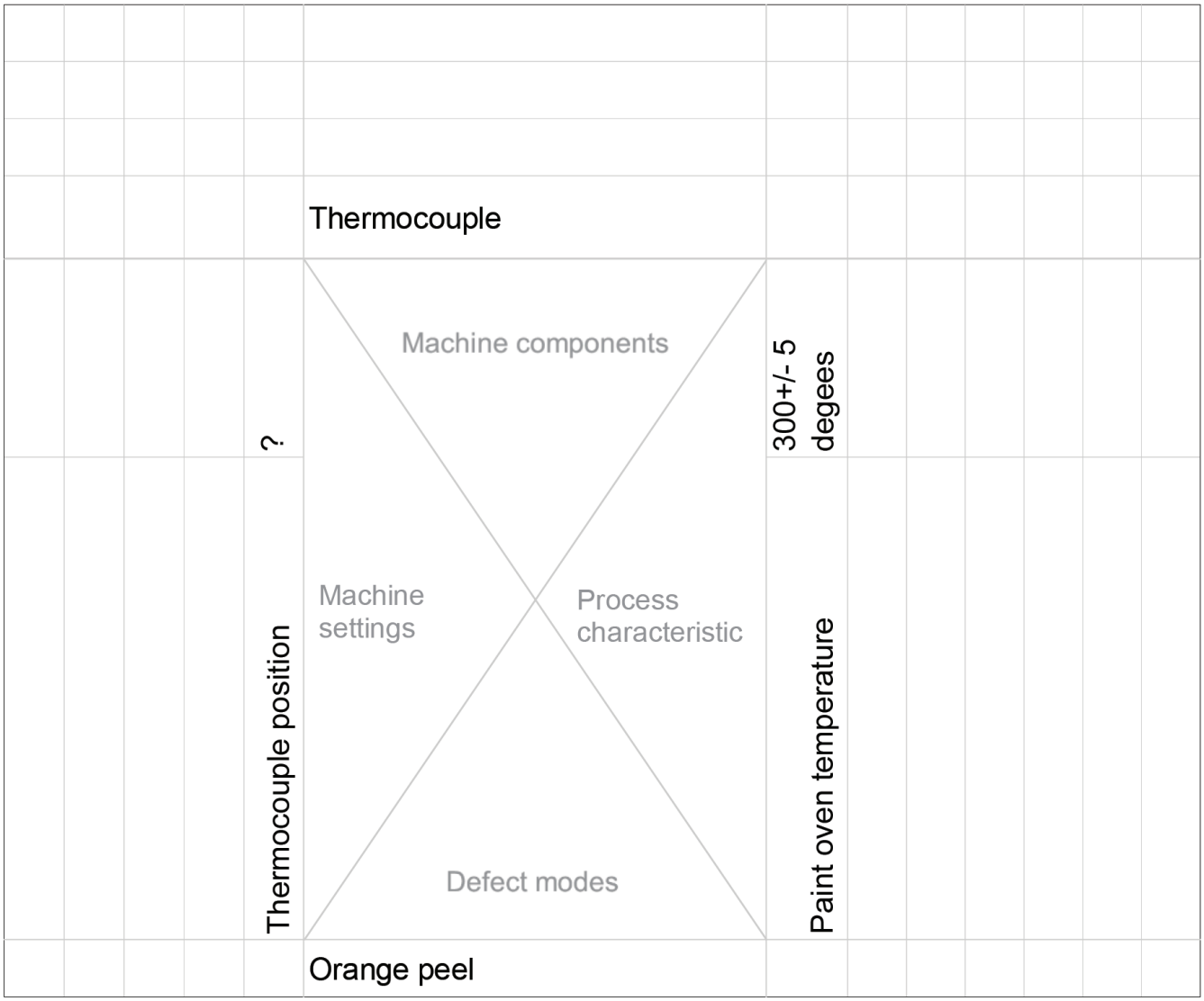
For key process parameters it should be verified that the equipment used to measure the parameter is calibrated and the process tolerance clearly defined.



The next task is to identify the machine components that influence the process parameter in question. In some cases there will be more than one machine component that affects the process parameter.

Next is to review that are the critical machine setting that is needed to ensure the defect does not occur. Again in complex processes there may be more than one for the machine component in question.

A simple example of the QX matrix is shown below. The example takes the Orange Peel defect from the QA matrix, which the team determined was likely to be cause by a lack of control of the “Machine”, (which in this case the paint plant used to paint the components)



The matrix begins by starting with the defect mode from the QA matrix. Then working anticlockwise the team review the critical process characteristics, in this example the temperature of the paint oven. However at the time the defect occurred, the process control records showed that the paint oven was within the defined tolerance.

The team then reviewed the machine and what machine components influence the process characteristic, in this example a thermocouple. Investigation showed that the thermocouple had been changed the day before the defect occurred. Reviewing the maintenance specification showed that the position of the

thermocouple was not specified, but is critical to determine the correct temperature in the oven. The correct positioning was determined, the dimension was defined and an adjustment made to the position of the thermocouple.

The final matrix, the QM matrix (similar to a control plan), captures all the relevant process and machine parameters to ensure no machine related defect occur in the journey to zero defects.

Whereas there are often many process and machine parameters needed to control a process, these tools can be used to identify special process or machine parameters that are critical to achieve zero defects or zero breakdown. In TPM these are often referred to as Q points and visualized on the machine to highlight to the operator the importance of controlling the parameter or machine setting in question.

Summary
The above is only a very simple example. However it has been proven during TPM implementation that this systematic approach to investigating the source of product defects, using these tools can help in defect reduction, particularly related to defects caused by the machine itself.

Ask the expert

Question:
One requirement of ISO9001:2008 that I have struggled with in the past is, what evidence an auditor will be looking for when they audit “Top Management” commitment. I now see that this requirement has changed to Leadership and Commitment in ISO9001: 2015. Will this change how auditors audit our management team and the questions they will ask?

Response from Quality Partner:
Many of us will be aware that in many ISO9001 or ISO/TS16949 certified companies “Management Commitment” really only comes once or twice a year at the time of the external audit, where the Managing Director greets the auditor, shows the policy, objectives and management review evidence and the auditor reviews and moves on.

I think ISO9001: 2015 requirements related to “5.1 Leadership and Commitment” are significantly more challenging, not only for Top Management but for external auditors, many of whom are not comfortable auditing the Top Management in an organization, maybe because they have never been in that position in industry.

A formal definition of leadership is the “process of social influence in which a person can enlist the support and aid of others in the accomplishment of a common task” and “the action of leading an organization or a group of people”. However, leadership is an intangible quality that really cannot be taught. It is more than something that a person does; it is more of what that person possesses.

ISO9000: 2015, the terms and definitions standard states “Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the organization’s quality objectives”

So how will external auditors audit this? Again we can find some help in ISO9000: 2015, where guidance is given under the heading “possible actions”:

- Communicate the organization’s mission, vision, strategy, policies and processes throughout the organization
- Create and sustain shared values, fairness and ethical models for behavior at all levels of the organization
- Establish a culture of trust and integrity

- Encourage an organization-wide commitment to quality
- Ensure that leaders at all levels are positive examples to people in the organization

My advice, rather than thinking about this from an auditing prospective, this guidance gives a good framework for Top Management to look in the mirror and question themselves on whether they meet the intent of these requirements.

In many companies, although the mission, vision and quality policy are defined and displayed in the reception area, they are not truly understood by employees, and often Top Management do not understand the true purpose of the Quality Policy and how it relates to the mission and vision and the quality objectives. Auditors, rather than spending lots of time reviewing the documents, will need to question employees at all levels, starting with Top Management, to test true understanding and especially how the Quality Policy links to their everyday work.

Now let's have a look at some of the auditable requirements in ISO9001: 2015, requirement 5.1 Leadership and Commitment"

5.1c states "Ensuring the integration of the quality management system requirements into the organization's business processes;"

I think this is a great additional requirement, but more difficult to audit. It challenges Top Management to ensure that Quality Management is integrated into all business activities and key to the organization success in meeting their business objectives. If this is effectively done, the management review should no longer be something done to purely satisfy the auditor, but becomes more a business review to ensure customer and internal objectives are met.

5.1 states "Promoting the use of the process approach and risk-based thinking;"

Again I think this is a great requirement. Whereas the process approach to Quality Management has been around since 2000, do Top Management really understand this? As well as challenging this, auditors should challenge how Top Management consider and manage the risks in all the business processes.

This will really test Top Management commitment related to the effective use of risk analysis tools such as feasibility review, Failure Mode Effect Analysis (FMEA), contingency/disaster recovery plans etc.

Summary
The changes, as well as posing a significant challenge also give a great opportunity to get Top Management to understand the benefits that can be achieved by embracing the true meaning of Quality Management and how they play a key role in the effective implementation.

Quality Partner can help support organizations in providing tailored in-house training to ensure Top Management understanding of the changed requirements and how to address within a process based Quality Management System. This can be either a half or one day course, or a longer workshop activity. For more information contact enquiries@qualitypartner.co.uk or call Paul Hardiman on +44(0)7341 845930.

Question:
My company is currently certified to ISO9001: 2008 for our non-automotive product and ISO/TS16949 for our automotive products.

With the issue of ISO9001: 2015 in September 2015 and the pending issue of ISO/TS16949 in late 2016, I was wondering when to start the transition process. Any advice would be appreciated.

Answer from Quality Partner:
Good question! Firstly let look at the ISO9001: 2015 transition process. Organizations have three years to make the transition, to September 2018. This means that the transition audit needs to have taken place, any corrective actions implemented and verified as closed and the certificate reissued. It is likely many organizations will wait to the last minute. This will give certification bodies a significant challenge to ensure they have adequate resources available, especially with ISO14001 going through a similar transition process.

For ISO/TS16949 the IATF work group have starting drafting the revised specification and it is anticipated that the revised document will be ready for issue around September 2016. ISO/TS16949 certified organizations will have two years to make the transition, i.e. Complete by September 2018.

So back to the question. Most certification bodies currently undertake one audit to cover both ISO9001 and ISO/TS16949 (although auditors have to ensure the ISO/TS16949 rules are met with respect to audit day calculations etc.). Given this my recommendation is not to upgrade to ISO9001: 2015 until after the issue of the revised ISO/TS16949 specification. However this does not mean do nothing.

ISO/TS16949 will be based on ISO9001: 2015 requirements. ISO9001: 2015 includes some significant changes, including the focus on risk based thinking, but is still fundamentally based on the process approach.

This means that if an organization has a process based Management System the overall structure of the system will not need to change.

However, while waiting for the ISO/TS16949 revision, an organization can start to review what they currently have in place to understand risk and opportunity, not just in the manufacturing process, but in all business processes.

ISO/TS16949 certified organizations will already be using tools such as feasibility review to consider the risks in taking on new business, FMEA for product and process risk, and contingency planning for considering the potential risks in ensuring delivery of products to meet customer requirements. The first question to ask is how effectively are these tools used and are they used for both automotive and non-automotive products?

Next is to consider each process in the Management System and what risks and opportunity there are, and how these are managed and controlled. This will ensure that when the revised ISO/TS16949 specification is issued, some of the fundamental systems will be in place to manage and control risk.

Attending the two day “A practical approach to risk based thinking” (see page 1) may be beneficial in understanding practical value added tools to identify and manage risk.

When the ISO/TS16949: 2016 is issued the focus can then be on reviewing and addressing any amended/ new requirements. Taking this approach will ensure that there is plenty of time to make a stress free transition to both ISO9001: 2015 and ISO/TS16949: 2016 in one audit, ideally in 2017 before the final stampede!