Quality Partner Newsletter

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Welcome to the fifth 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:

- ISO9001: 2015 no longer has a requirement for maintaining a quality manual. Should we throw it away?
- How effective is your contingency plan? This edition explores the purpose of a contingency plan and how it can help in ensuring an organization can fulfill customer requirements.

Ask the expert:

- We have a number of qualified internal auditors to undertake internal audits against ISO/TS16949: 2009. What training will these auditors need given the pending changes in ISO/TS16949?

- Why do we have a low R&R but still have measurement issues?

- We currently have a defined Management Representative. I see this role has disappeared in ISO9001: 2015. Does this mean this person no longer has a job role?

- I have heard of the TPM tool called a QA matrix. Can you explain the link between this and PFMEA?

For more information on any Management System or TPM training visit: www.qualitypartner.co.uk

Quality Partner Activities

TPM Integration

Quality Partner has been supporting a major multinational client in providing training on how to integrate their Quality Management System into their TPM programme. Like many companies up until now TPM and ISO9001 have been run completely separately, resulting in wasted time and duplication of effort.

For more information on how Quality Partner can support your organization contact Paul Hardiman on
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Since the development of the first version of ISO9001 in 1987 there has been a requirement for an organization to establish and maintain a Quality Manual.

For many organizations the way this requirement was addressed was to write a manual around the clauses of the standard, simply replacing the word in the standard “an organization shall….” to “we will…” Normally the only time this document was referred to was during external audits, with auditors who suffer dust allergies having major problems!

With the development of a process based management system standard, first issued as ISO9001: 2000, organizations had to ensure the Quality Manual that covered:

a) The scope of the quality management system, including details of and justification for any exclusions
b) The documented procedures established for the quality management system, or reference to them, and
c) A description of the interaction between the processes of the quality management system.

Again, while organizations maintained a Quality Manual, many struggled in understanding the purpose of it and how it could be used as a useful document to them.

With the issue of ISO9001: 2015, the requirement for having a document called a Quality Manual disappeared. 7.5.1 states as a note (Guidance)

“The extent of documented information for a quality management system can differ from one organization to another due to:

- The size of organization and its type of activities, processes, products and services;
- The complexity of processes and their interactions”

Should an organization throw the Quality Manual away?

Before doing this there are some key questions to consider:

- If a potential new customer asks for information about your organization and the Quality Management System you operate what would you send them?
- When you take on new employees how do you make them aware of the Quality Management System and its structure?
- If the Quality Manual does not exist, how do employees/auditors find their way into the Quality Management System structure? (processes, procedures, work instructions etc.)

An additional consideration, it is likely the revised version of ISO/TS16949, due for publication in late 2016, will continue to require a Quality Manual. In addition to the existing requirements defined in ISO/TS16949: 2009, it is likely the Quality Manual will also need to address how Customer Specific Requirements are addressed within the Quality Management System.

This may be an ideal time to instigate discussions on how a document can be created that, as well as meeting the relevant standard requirements, can be a useful tool for internal and external communication (to potential new customers, interested parties, new employees etc.).

As an input to this discussion you may want to consider including in any manual the following:

- An overview of the organization, including scope of activities and capabilities
- The strategic direction of the organization linked to the Quality Policy
- A diagram showing the sequence and interaction of the processes within the Quality Management System with a short explanation on how risks are identified and managed
- An overview of the Quality Management System structure, including a link to addressing customer specific requirements. This would be a signpost into the rest of the QMS

As the above is unlikely to change regularly, there is the opportunity to consider involving marketing, and making this a “glossy” brochure, with artwork to encourage people to want to read, or publish electronically thought the internet. And remember, there is no need to mention any clauses, or use standard jargon!, make it work for you.

Contingency Plans

Since the development of ISO/TS16949 in 1999 organizations in the automotive supply chain have had to meet the requirement to have a documented contingency plan.

The current requirement in ISO/TS16949: 2009 states:

“The organization shall prepare contingency plans to satisfy customer requirements in the event of an emergency such as utility interruptions, labour shortages, key equipment failure and field returns.”

Whereas all 65,000 ISO/TS16949 certified organizations will have a contingency plan, how effective are they?

To measure effectiveness, the first indicator we need to look at is delivery performance to the customer. Providing the customer 100% on time delivery without disruption would be evidence that contingency planning is effective, but also we need to consider risk.

A risk in meeting customer requirements is the robustness of the supply chain to supply sufficient products and materials. As part of the contingency planning process we need to understand the risks (e.g. Single source suppliers, suppliers in vulnerable regions etc.).

ISO/TS16949 requires an organization to identify and monitor the incidents of premium freight. High incidents/cost of premium freight could indicate underlying issues which could affect supply to the customer (e.g. Poor production planning process).

With the increased emphasis in ISO9001: 2015 on Risk Based Thinking, the contingency plan will be of even more relevance to an organization and auditors in the revised version of ISO/TS16949.

So, if an organization is looking to strengthen their contingency plan how should it be approached? Firstly look at what is already in place. Organizations will often have documents that will not be called contingency plans (e.g. Business continuity or disaster recovery plans) but will be useful inputs.

Next thing to consider is how to identify:

- Internal and external risks to all manufacturing processes, infrastructure equipment and product/ material supply essential to maintain production output and to ensure that customer requirements are met.

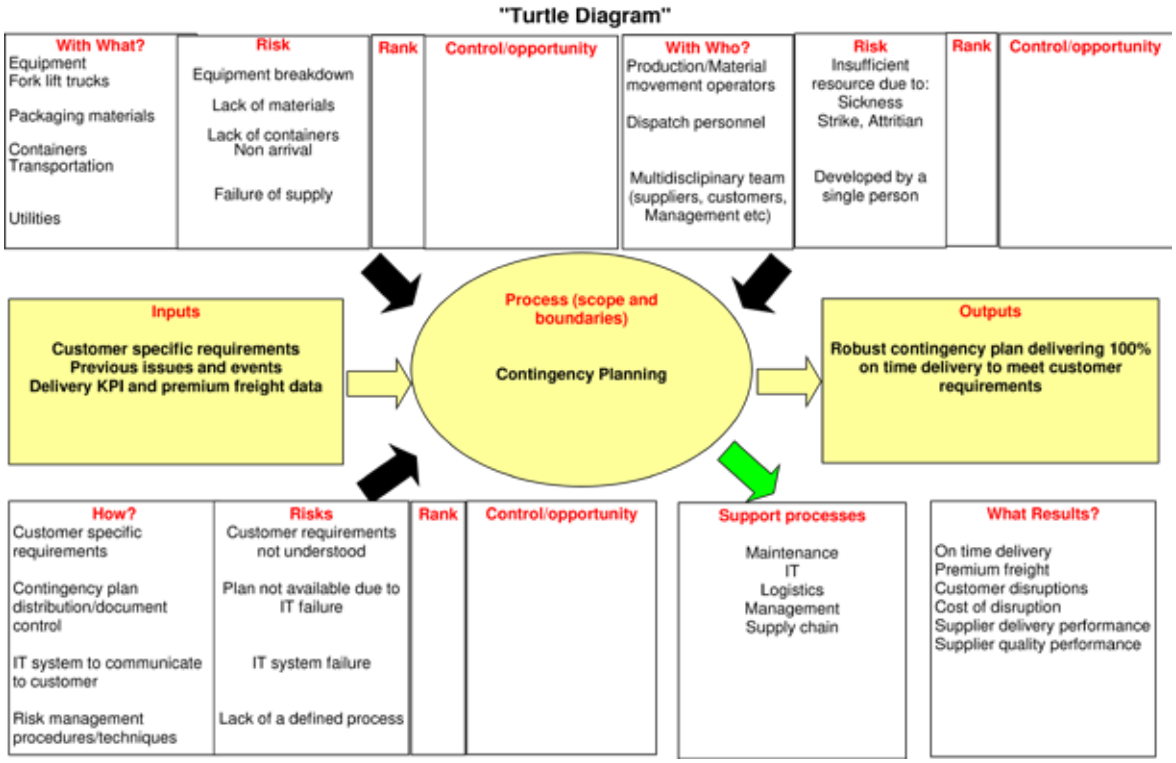
ISO9001: 2015 or any automotive additional requirements will not specify how to do this. Techniques that could be used are:

- Brainstorming
- Questionnaires
- Industry benchmarking
- Scenario analysis
- Risk assessment workshops
- Auditing and inspection
- FMEA
- Fault tree analysis

However, the turtle diagram, which many automotive suppliers will already familiar with could be used to stimulate discussion. The modified turtle diagram introduces consideration of risk in the process.

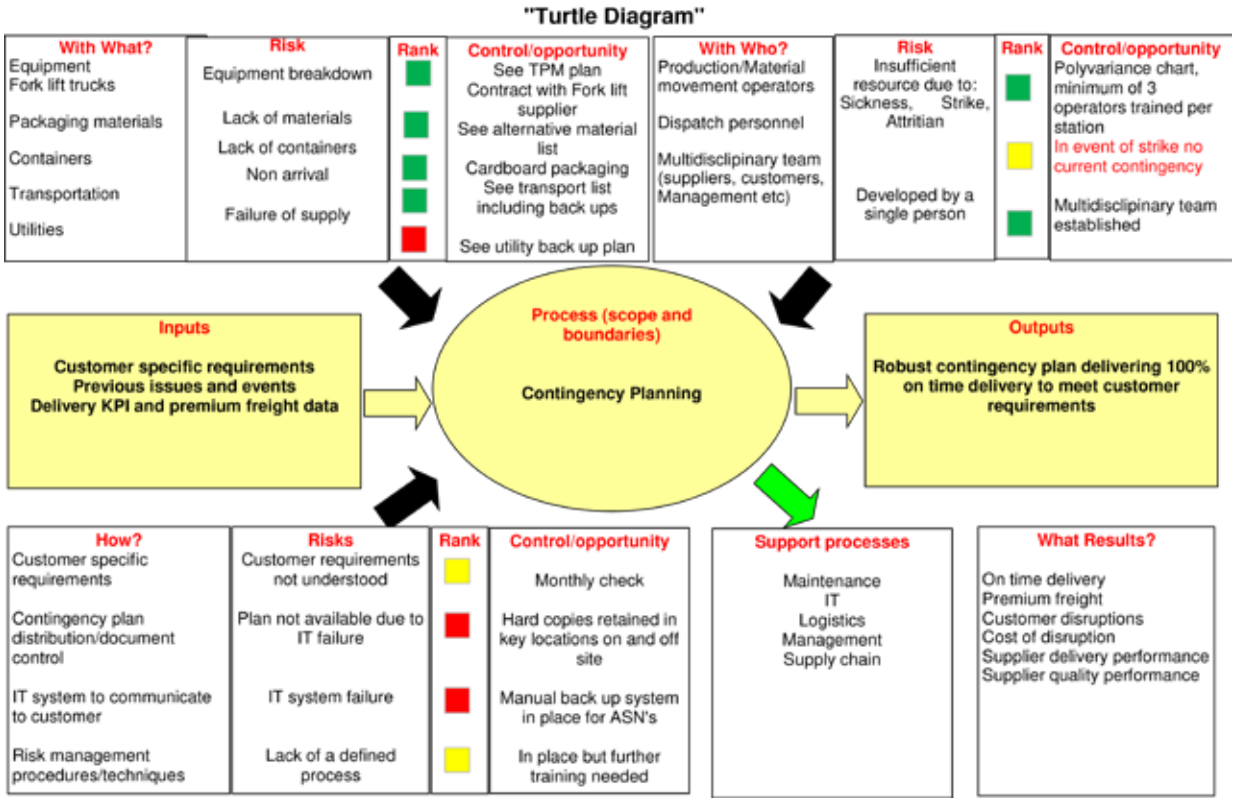
The first stage would be to think of contingency planning as a process and what is needed to ensure it is effective and efficient in meeting the customer and organization requirements. Then we need to consider

A simple example of a turtle diagram is shown below, but for real this would be more complex. It would be best to do this with a multidisciplinary team with involvement of management from the relevant areas.



The next thing is to consider what poses the greatest risk. A simple red, yellow and green system could be used, with red being the highest, yellow intermediate and green low risk.

Then we need to think about the contingency in place, which could be an existing control, or an opportunity to improve the control and reduce the risk. Again a simple example is shown below:



Once the contingency plan is developed it needs to be subject to ongoing review.

An organization should consider periodically testing the contingency plans for effectiveness (e.g. simulations, as appropriate and practical!). For this to be effective the organization needs to provide effective training to all relevant employees to ensure they know how to react in the defined situations.

It is recommended that contingency plan reviews are undertaken, on an annual basis as a minimum, using a multidisciplinary team and the plan is updated as required based on events or change in risk factors.

Finally, the contingency plan needs to be a controlled document and circulated in a format that can be readily retrieved in the event of an emergency.

Ask the expert

Question:
We have a number of qualified internal auditors to undertake internal audits against ISO/TS16949: 2009. What training will these auditors need given the changes in ISO9001: 2015 and pending changes in ISO/TS16949?

Response from Quality Partner:
You will need to demonstrate auditors are competent in the concept of the process approach to auditing incorporating Risk Based Thinking, and the changes in the standards, but not necessarily retraining.

Firstly let's look at System Audits. To undertake an effective system audit auditors need to be able to:

a) Understand and apply the automotive process approach for auditing, including risk-based thinking
b) Understand applicable customer-specific requirements
c) Understand the revised ISO/TS16949 automotive specification requirement
d) Understand applicable core tool requirements related to the scope of the audit
e) Understand how to plan, conduct, report, and close out audit findings

If you have existing qualified auditors the likelihood is you should be able to demonstrate they are competent against b), d) and e). However, refresher training may be needed to coach auditors on how to incorporate Risk Based Thinking into audits and to understand additional requirements introduced by the move to ISO9001: 2015 and any additional IATF new automotive specification requirements.

For Manufacturing Process Audits, in addition to the above competencies, auditors need to have a detailed understanding of how to use the PFMEA and Control Plan to verify effective process controls to ensure product is manufactured to specification.

For Process Audit, the emphasis is more on the competency to read product drawings and specifications, and use the relevant measuring and test equipment to verify the relevant product characteristics.

Finally, an area often overlooked is the competency needed to undertake effective second party audits. Firstly we need to ensure that auditors meet the requirements defined in any Customer Specific

Requirements. Next we have to consider the role of the second party auditor. Is it to just verify conformance to standard, or is it to assist suppliers in making improvement.

If it includes the latter, we need to ensure that auditors are competent to do this. For examples, auditors may need to understand lean manufacturing principles as well as other improvement methodologies (e.g. TPM).

Quality Partner has developed a two day Auditor Transition course for existing ISO/TS16949 auditors, designed to be delivered at an organization's premises, which includes case studies and live audits as appropriate.

For new auditors a three day course is available.

For more details contact Paul Hardiman at paul.hardiman@qualitypartner.co.uk or +44(0) 7341 845 930.

Question:
We measure a special characteristic using a micrometer. We undertook a Gauge R & R study using three normal users of the equipment. We got a low gauge R & R % (7.6%) with a low appraiser variation contribution and a good Number of Distinct Categories (ndc). However we know from customer issues and internal concerns that we have measurement issues. We suspect that this is down to operator issues in using the micrometer, but are confused why we have such good MSA results.

Answer from Quality Partner:
The first thing to consider the effectiveness of the operator training undertaken to verify they now how to use measurement equipment correctly. This should have been done before any MSA studies are undertaken.

The next issue is that the Gauge R & R study, using parts from the normal production process, only gives an indicator on within appraiser variation (Repeatability) and between appraiser variation (Reproducibility), not that the values are the "true" sizes of the parts measured. If, for example, each appraiser is consistent with themselves and with their colleagues, irrespective of the whether the actual measured value is "true", the Gauge R & R will be low. (For example they may all be applying too much pressure to the micrometer and not using the ratchet, so all values are low, but consistent).

That is why measurement system analysis is more than just Gauge R & R. In this case, rather than measure parts where the value is not known, it may be worth getting operators, as part of their training, to undertake measurements against a known Reference Standard (Where the value had been established using a more accurate instrument under laboratory conditions).

If one reference standard is used this would be a bias study and if multiple reference standards of different sizes across the normal measurement range, this would a linearity study. Before undertaking the studies, it should be verified that the measuring equipment is calibrated and in good condition, to eliminate possible equipment error. If large bias or linearity errors are detected this may indicate further employee training is needed.

For practical onsite training in MSA, where delegates do not only learn the theory but get the opportunity to apply their knowledge through practical learn by doing case studies and exercises, contact paul.hardiman@qualitypartner.co.uk or call +44(0) 7341 845 930

Question:
We currently have a defined Management Representative. I see this role has disappeared in ISO9001: 2015. Does this mean this person no longer has a job role?

Answer from Quality Partner:
You are right, ISO9001: 2015 does not have a requirement to have a defined Management Representative. I think this is to promote that a Quality Management System (QMS) should not be owned and managed by just one individual, often the Management Representative, but responsibilities should be spread throughout the organization.

However, clause 5.3 requires that ”responsibilities and authorities are clearly defined, including responsibility to make sure the (QMS) is effectively implemented and maintained and reporting on the performance of the QMS.”

If the implementation and sustainability of the QMS is to be effective responsibility has to be driven down to the process owners, not just reliance on one person, the Management Representative.

There would be no issue if you continue to show a Management Representative in your organization structure, responsible for overseeing the effective maintenance of the QMS, but auditors are being pushed more and more to question process owners and people working in a process to verify their understanding, rather than just the Management Representative answering all the questions!

Question
I have heard of the TPM tool called a QA matrix. Can you explain the link between this and PFMEA?

Answer from Quality Partner:

The QA matrix is one of the possible tools to use in the deployment of the Quality Maintenance pillar of TPM, or if you want to focus on defect reduction. The simple QA matrix looks at the relationship between the steps of a manufacturing process and where the most likely or actual source of the defects comes from. The matrix can be created using customer complaint or internal defect data, over any period of time.

Organisation		QA Matrix	Created By
Area			
Date			

Defect modes Impact	Processes							Total occurrences by defect mode
	Lattice	1st nip	2nd nip	3rdnip	Exit nip	Transfer chute		
Wood contaimnation								
Oil contamination								
Burnt cotton								
Clumping								
Short fibre								

Once the data is gathered and discussed by the team, the next stage is to consider the most likely contributing cause of the defect, related to the 4M condition (Man, Method, Material and Machine).

Organisation		QA Matrix	Created By
Area			
Date			

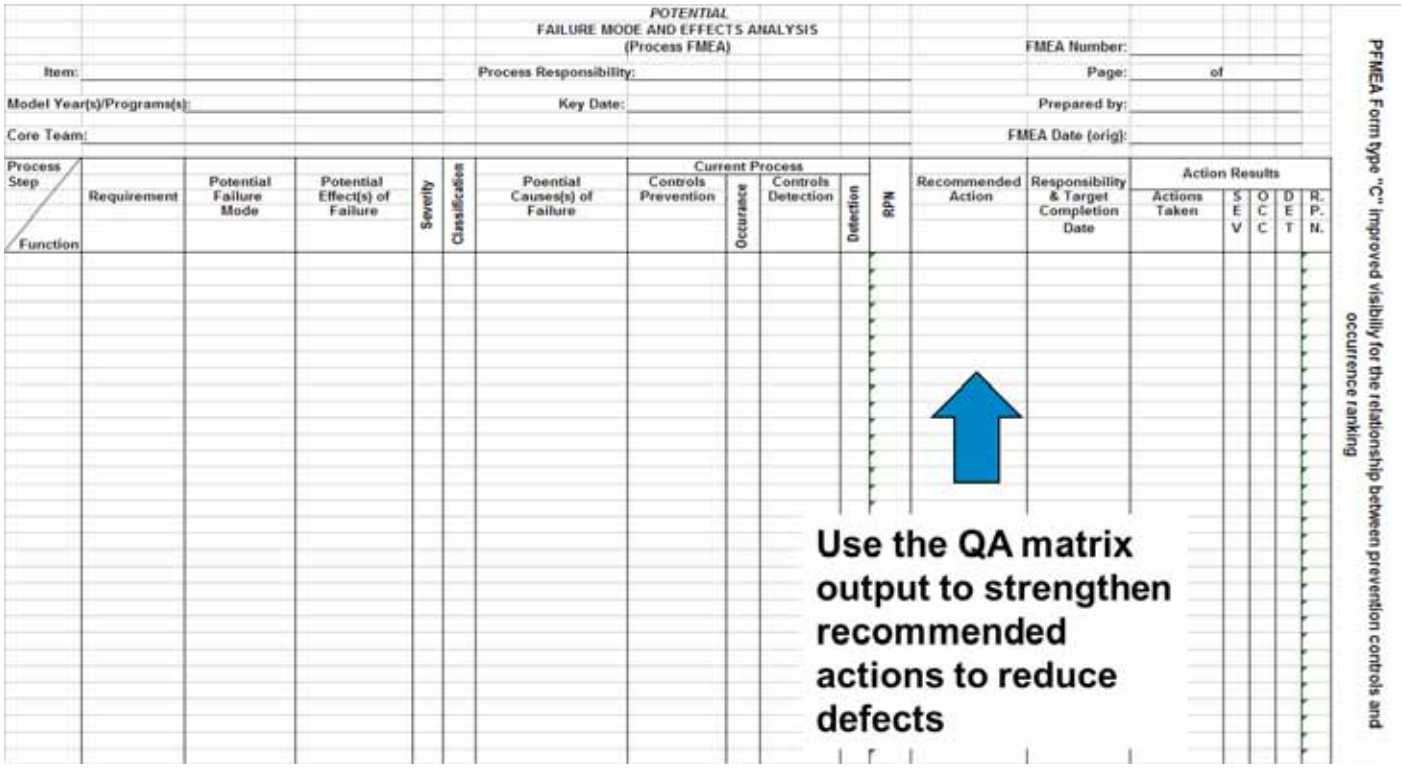
Defect modes Impact	Processes																								Total occurrences by defect mode
	Lattice				1st nip				2nd nip				3rd nip				Exit Nip				Transfer chute							
	Man	Mat	Mth	Mc	Man	Mat	Mth	Mc	Man	Mat	Mth	Mc	Man	Mat	Mth	Mc	Man	Mat	Mth	Mc	Man	Mat	Mth	Mc	Man	Mat	Mth	Mc	
Wood contamination																													
Oil contamination																													
Burnt cotton																													
Clumping																													
Short fibre																													

For man, method and material normal problem solving tools can be used to focus on defect reduction, whereas with defects that are likely to come from the machine, a QX matrix is used.

So one question I am often asked, “If we already have a Process Failure Mode and Effects Analysis (PFMEA), would we get any benefit in using a QA matrix?”

If you are at zero defect then there maybe no benefit, but for most organizations that is a long term dream!

By understanding the key sources of defect, it gives an opportunity to go back to the PFMEA and critically review those stages of the process, further discuss the risks (Severity, Occurrence and Detection) and how defect prevention can be achieved. This gives a fresh prospective to the PFMEA and will help to strengthen “Recommended actions” that are often not robust or seen to conclusion.


POTENTIAL
FAILURE MODE AND EFFECTS ANALYSIS
(Process FMEA)
Item:
Process Responsibility:
FMEA Number:
Page: of
Model Year(s)/Programs(s):
Key Date:
Prepared by:
Core Team:
FMEA Date (orig):
Process Step / Function
Requirement
Potential Failure Mode
Potential Effect(s) of Failure
Severity
Classification
Poential Causes(s) of Failure
Current Process
Controls Prevention
Occurance
Controls Detection
Detection
RPN
Recommended Action
Responsibility & Target Completion Date
Action Results
Actions Taken
SEV
OCC
DET
R.P.N.
Use the QA matrix output to strengthen recommended actions to reduce defects
PFMEA Form type "C" Improved visibility for the relationship between prevention controls and occurrence ranking