

Quality Partner Newsletter

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Welcome to the fourth 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:

- ISO14001 utilizing the process approach.
The article looks at the requirements of ISO14001: 2015 and explores ways to take a fresh look at meeting the requirement by focusing on the process approach and risk based thinking.
- Organizational knowledge. ISO9001: 2015 has a requirement for an organization to determine the knowledge necessary for the operation of its processes and to achieve conformity of products

and services. This article explores ways that an organization can provide evidence to show that this is effectively implemented.

- Ask the expert:
 - How can we strengthen our internal audit process to be more effective?
 - Process effectiveness verses efficiency, what is the difference?
 - Revision process for ISO/ TS16949. What are some of the likely changes?

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

Quality Partner Activities ISO14001: 2015

Quality Partner has further added to the range of courses available including a two day ISO14001: 2015 Internal Auditor course.

Whereas many ISO14001 courses focus on teaching auditors to check compliance with procedures, the Quality Partner course focuses on auditing processes for their effectiveness. Read the full article on pages 2-5.

VDA6.3

Paul Hardiman, one of the most experienced trainers in the world, has become a licensed trainer with GAB to deliver VDA6.3 Process Audit training and other VDA-QMC courses to clients anywhere in the world.

ISO14001: 2015. How to develop an effective process based management system focused on risk based thinking

Many organizations who have implemented Environmental Management systems, to meet the requirements of ISO14001: 2004, have developed their systems around the clauses of the standard, rather than the business processes. Whereas the Management Representative may understand the structure and where to find things in the system, often employees do not understand the system and how it applies to them and their every day jobs.

In addition, environmental aspects and impacts are often developed in isolation, again based on those that affect the whole organization, rather than applying to the organizations specific business processes.

ISO14001: 2015 gives an ideal opportunity to revisit this, and to develop an environmental management system suitable to meet the requirements of all interested parties. It is also a good opportunity to evaluate whether to integrate Quality and Environmental systems using the common framework of ISO9001: 2015 and ISO14001: 2015.

How do we start the transition?

Firstly purchase the standard. Shop around, prices can vary massively, ranging from £50 (70 USD) up to a ridiculous £200 (283 USD)!

Next take a look at the existing system, talk to employees and find out if they think it is relevant and understandable. Review the internal audit results, question if issues are being found and if audit results match the actual environmental compliance in the organization.

If your organization already had a process based quality management system that may be a good place to start the transition.

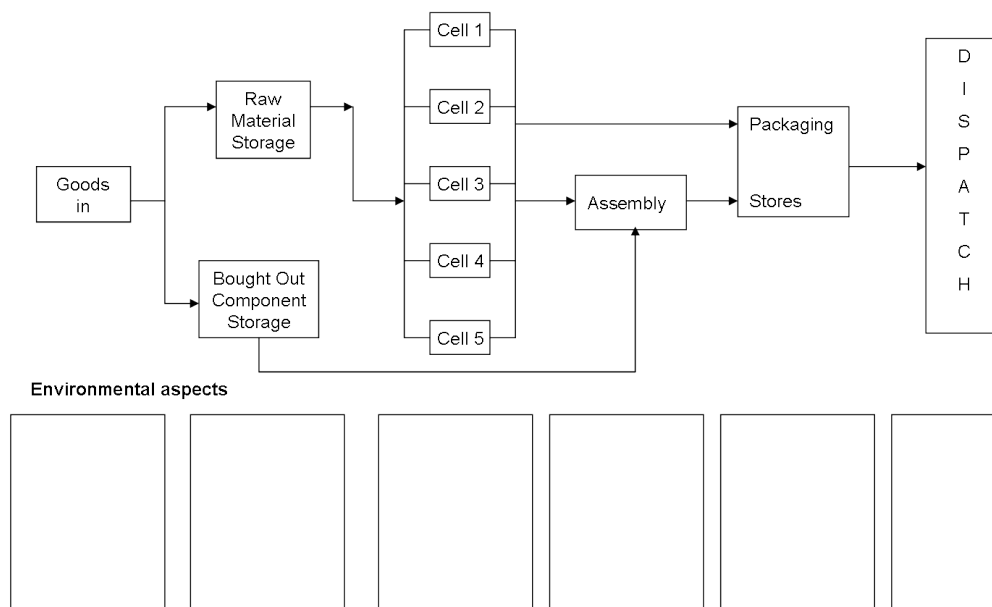
ISO14001: 2015 requirement 5.1 Leadership and commitment states:

“Top management shall demonstrate leadership and commitment with respect to the environmental management system by: Ensuring the integration of the environmental management system requirements into the organization’s business processes.”

If the processes in the organization quality management system already cover all the activities of the organization, then all the environmental aspects and impacts must in some way link to these processes. This may be a good opportunity to get the involvement of employees, ask them to participate in the discussions on which aspects and then apply to their process, whether they are aware of the environmental impact and how the situation is controlled in practice to minimize any negative impact on the environment. An example template is shown below for the manufacturing process. Although the thinking maybe simple, having used this on several training courses, not only does it start to get more employee engagement, it stimulates debate about how to improve the environmental controls.

The output of the exercise can be compared to the existing aspects and impacts register to check alignment.

Process Flow - Manufacturing



Next is to think about risk and opportunities requirements in ISO14001: 2015, where there are many common requirements with ISO9001: 2015.

Risk is not a new concept, risk based thinking would have been used by organizations to determine significant environmental aspects, often using a probability and impact ranking system. An example ranking table is shown below.

		Impact				
		Very Low 1	Low 2	Medium 3	High 4	Very High 5
Probability	Very High 5	5	10	15	20	25
	High 4	4	8	12	16	20
	Medium 3	3	6	9	12	15
	Low 2	2	4	6	8	10
	Very Low 1	1	2	3	4	5

However, in ISO14001: 2015 the requirements for understanding risk is broader, 6.1.2 requiring an organization “determine the risks and opportunities, related to its environmental aspects (see 6.1.2), compliance obligations (see 6.1.3) and other issues and requirements, identified in 4.1 (Understanding the organization and its context) and 4.2 (Understanding the needs and expectations of interested parties).”

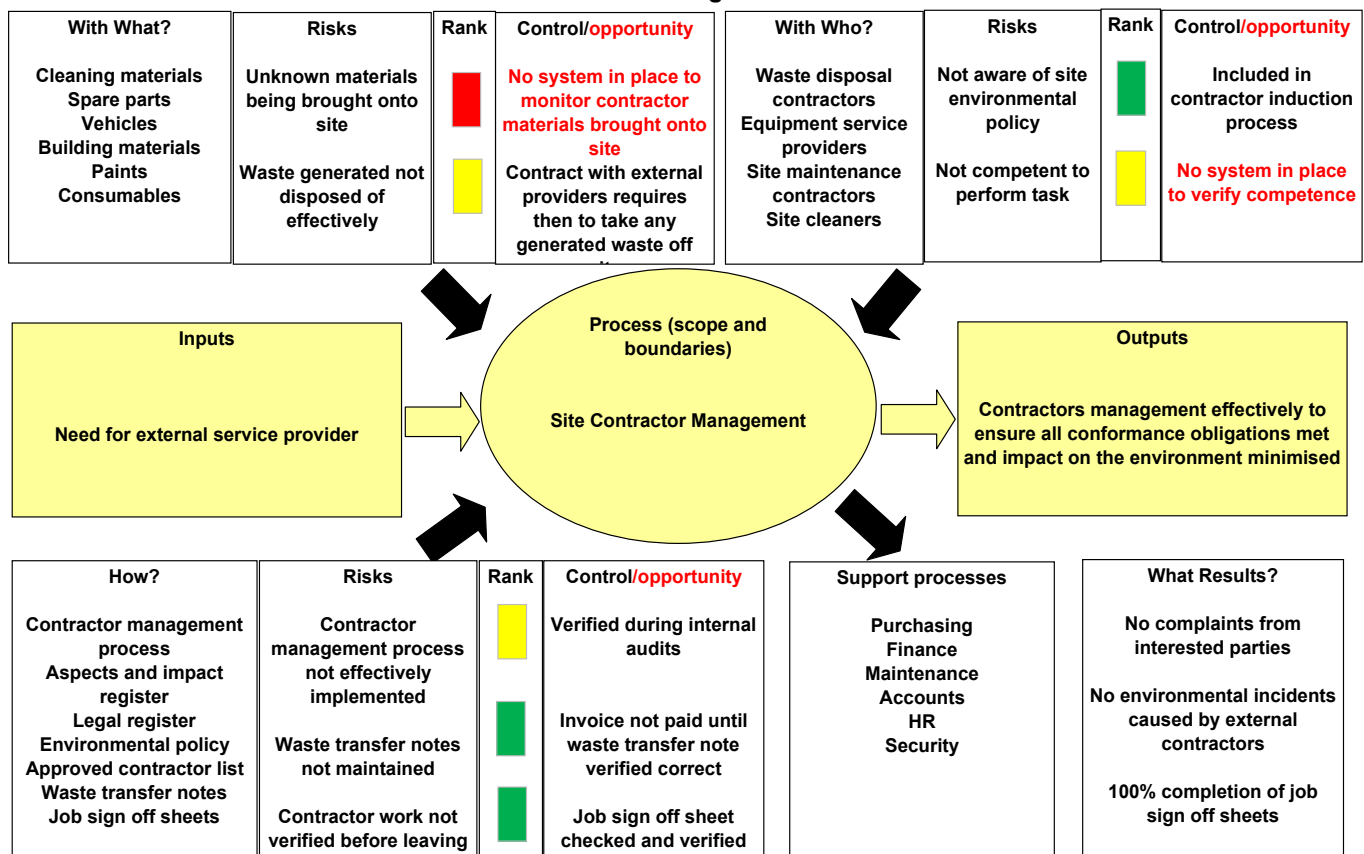
Again this is an ideal opportunity to get the involvement of employees in all of the processes to help identify risks and also opportunities.

ISO14001: 2015 does not define any specific process or method for identifying risk and opportunity.

Many organizations, especially those who have implemented ISO/TS16949, will already understand the concepts and use of the “turtle diagram”.

One method of thinking on risk and opportunity could be to use a slightly modified turtle diagram. A simple example for contractor management is shown below. The advantage of using the turtle diagram is that it encourages an organization to look at risk and opportunity from a process prospective. It also drives ownership to the person responsible for the process, and it makes the team think about risks and opportunity related to people (with who), risks related to the physical (with what) and risks related to the systems and methods (How) to ensure the process can meet the desired results.

"Turtle Diagram"



The above example uses a red, yellow and green ranking system, but other methods can be used to suit individual organizations.

The opportunities marked in red in the control/opportunity boxes can then be tracked for completion to improve the overall effectiveness of the environmental management system.

The other benefit of the turtle diagram, is it can be used as a basis for auditing the processes within the environmental management system.

In a recent onsite ISO14001 internal auditor course delivered by Quality Partner, this “fresh approach” to

environmental management systems, in which the modified turtle was used in audit preparation, identified 12 major nonconformities and 6 minor nonconformities, as well as 4 opportunities for improvement during some “mini live audits” on the second day of the course. The issues identified were not new, but had not been picked up in the traditional clause/procedure based audits.

I think most organizations reading this article will already be certified to ISO14001: 2004, but I challenge you to be self-critical on whether the system is adding value, and really delivering the intended results to all interested parties.

If not, then use ISO14001: 2015, which is written in plain common sense English, to drive the change in thinking and enhance employee engagement.

Those looking for more information, it may be worth researching Knowledge management (KM). Knowledge management (KM) is the process of capturing, developing, sharing, and effectively using organizational knowledge. It refers to a multi-disciplinary approach to achieving organizational objectives by making the best use of knowledge.

For more information on the training available related to ISO14001: 2015 contact enquiries@qualitypartner.co.uk or call +44 (0)7341 845 930.

Organizational Knowledge

ISO9001: 2015 has added a new requirement related to Organization Knowledge.

Clause 7.6 states: “The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge shall be maintained and be made available to the extent necessary.

When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.”



Organizations who are already certified to ISO9001: 2008 will already have some “documented information” to support compliance with this requirement, but making the transition to ISO9001: 2015 gives an opportunity to question the effectiveness of existing systems.

Let’s think about some examples where organizational knowledge is critical. Many of us can remember in the global recession in 2008-2010 that organizations had to downsize to survive. In those organizations, in the weeks after the downsizing, I wonder how many examples you could quote where tasks, some which on the surface seemed simple, could not be completed effectively as the person(s) with the knowledge had left the organization. In many cases, this did not just affect the organization effectiveness, but also customer satisfaction. I was told an example in a small second tier automotive supplier where the simple task of

entering a customer purchase order and production schedule could not be entered into the production planning system, because the “key” person had been involved in an accident and was not able to go to work. A member of the organization management team actually had to visit the person in hospital to gain the necessary information to perform the task.

So in looking at this we need to approach it with “Risk Based Thinking” in mind.

Some questions to ask in understanding current situation could be:

- What knowledge do we want to retain?
- How do we currently retain this information?
- If knowledge is retained by people how do we ensure back up person(s) is/are available?
- If knowledge is intellectual property how do we retain and protect this?
- If knowledge is retained as documented information (documents and records, hard copy and electronic) how do we protect this from damage, deterioration or loss?
- How do we ensure we retain knowledge gained from external sources (e.g. equipment manuals, course training manuals, standards, drawings etc.)

While many organizations will be able to provide adequate documented information to demonstrate compliance with the requirement in the manufacturing process (skill matrix, work instructions etc.), there may be gaps in other processes (especially support processes) that need to be addressed.

This does not mean creating hundreds more work instructions, creating more skills matrix or developing more complex back-up systems, but it does mean understanding and managing risks in management of knowledge.

The process to maintain knowledge is ongoing. Organizational knowledge could be “added or updated dynamically”, so the process needs to address this and the effectiveness reviewed during periodic internal audits.

Ask the expert

Question:

We are looking to further develop our internal audit process, especially the competence of internal auditors. Are there any changes likely in the forthcoming revision of ISO/TS16949 that we should take into consideration?

Response from Quality Partner:

I think many organizations would agree that there is lots of potential opportunity for improvement in further developing the internal audit process.

Firstly, ISO/TS16949 has led to some confusion in defining three types of audit, system, process and product. This is unlikely to change in the forthcoming revision to ISO/TS16949 but the difference between the three types may be clarified.

Let's look at the three types and the competencies that are required for each:

1. System audits:

These audits are to verify the effectiveness of the quality management system to meet the requirements of ISO9001: 2015, any additional automotive requirements and customer specific requirements.

The quality management system should be based on the processes of the organization and risks and opportunities within the processes should be understood and managed. Therefore, system audits should not be based on a clause by clause approach, or using a fixed checklist, but should utilize the process approach to auditing. So the first competency any internal auditor should have is a thorough understanding

of undertaking an audit using the process approach. Secondly, if effective audits are to be undertaken, the auditor should be competent in the automotive core tools and understand internal and external customer specific requirements, the requirements of ISO9001: 2015 and additional automotive requirements and be able to evaluate audit results.



2. Manufacturing process audits:

These audits are specifically to verify the effectiveness and efficiency of the manufacturing processes, including linkages to the relevant support processes.

Analysis of third party audit findings show that one of the highest reason for nonconformities is the lack of effective implementation of the PFMEA and control plan, including the linkages to work instructions. So if manufacturing process audits are to be effective, the audits have to be planned by the steps of the manufacturing process, have to cover all shifts and have to include a detailed check

that the PFMEA, control plan and work instructions are aligned and reflect reality. Audits should include checks that all the controls that detection are based on in the PFMEA are linked to the control plan, that any mistake proofing devices are periodically verified and that measuring equipment is calibrated.

So what standard should be used for these process audits and what competencies should an auditor have?

Firstly why re-invent the wheel in developing checklists when there are proven process audit tools available. VDA6.3 Process audit is one of the most widely used, in many cases it is mandated by German auto makers. Chapter 6.5 covers detailed requirements for production and is based on a series of questions based on the turtle diagram. Each question is evaluated and scored 0, 4, 6, 8 or 10 based on the evidence collected. The audit can be done by the overall production process or by process step. At the end of the audit an overall % score is calculated, allowing benchmarking between the processes. Other reference documents that could be used are AIAG CQI 8, layered process audit, FIEV 2.0 Production process audit manual, or MMOG-LE (Materials Management Operations Guidelines Logistics Evaluation).

Section 3 of VDA6.3 defines auditor competence requirements, including knowledge of Quality Management Systems and industry/manufacturing process experience.

3. Product audit

Product audits are to verify that products meet all specified requirements at appropriate stages of production and delivery. These are not the checks undertaken by operators specified in the control plan (as operators undertaking a check of their own work does not fulfill the audit requirement for independence), but additional independent checks to verify that product meets the defined requirements.

The methodology used to plan and undertake these audits has to be defined, along with auditor competence requirements. Good guidance on developing a product audit plan and undertaking product audits is given in VDA6.5, product audit.

Regarding auditor competence, auditors, as well as having a detailed understanding of the manufacturing process, need additional competencies including how to read drawings, how to use measuring equipment and how to evaluate audit results.

Summary

So, with the pending revision of ISO/TS16949 now is a good time to reflect on your current internal audit process, questioning its strengths and weaknesses. In looking at this, it would be good to check the alignment of the internal audit results with the issues found in third party or customer audits.

Next is to think about who will undertake the audits and what are the competencies required (i.e. will all audits be done by the same group of people, or will there be a different group of auditors defined for system, process and product auditors). Selecting the right training provider to further develop auditors is essential, as you will need to provide evidence to the third party auditor that the trainers used to deliver the training are themselves competent.

Quality Partner can provide auditor training to meet all your training needs.

We will shortly have available training in the revised ISO/TS16949, both for new auditors and existing auditor transition as well as courses in undertaking effective process audits using VDA6.3, product audits using VDA6.5 or process and product audits combined.

Courses can be tailored to meet an organization's specific requirements, including practical audits when done at your premises. Exams to verify auditor competence can be added on request.

For more information contact enquiries@qualitypartner.co.uk or call +44 (0)7341845930.

Question:

We had a nonconformity in a recent ISO/TS16949 external audit related to clause 5.1.1 'Top management shall review the product realization processes and the support processes to assure their effectiveness and efficiency.'

While we had a list of key performance indicators (KPI's), due to a recent reorganization the indicators were not aligned to our revised process structure, and some processes had no KPI's.

Can you offer the best way to address this, especially as I am experiencing resistance from the management team to add to the high level KPI list?

Answer from Quality Partner:

This is an issue I have seen many organization's face. Many think that the requirement means that a separate indicator is needed for effectiveness and efficiency for each process and that these indicators must be called KPI's (for examples if 20 high level processes are defined, 40 KPI's are needed). The requirement does not say this.

For example, one KPI may apply to more than one process and some measures may not be defined as KPI's, but lower level indicators managed locally by the process owner.

Let's look at the difference between effectiveness and efficiency. Effectiveness is the planned results of a process are achieved, which tends to focus on achieving customer (internal or external) satisfaction. Efficiency is the results achieved verses the resources used.

An example for a product realization process: For an external logistics process, effectiveness may be measured by on time delivery, while efficiency could be incident of premium freight. But the process owner may also have other indicators, not defined as KPI's but used to monitor the process, for example ASN accuracy, pick efficiency etc.

For a support process let's consider the IT process. This time the customer would be more the internal customer rather than external. What are the internal customer needs? They want hardware and software that meets their needs, as well as their customer needs, and resolves problems in a timely manner. So, an



effectiveness measure could be response time and an efficiency measure IT spend to budget. Also a measure such as Overall Equipment Efficiency (including its components) may be used an indicator for more than one process, for example production scheduling, production and maintenance.

It would be good practice, to assisting in providing evidence to an external auditor, to create a matrix with each high level process and how the effectiveness is monitored.

As part of management review, Top Management need to show evidence they have reviewed each of the high level process performance, using the KPI's or other lower level indicators. This does not have to be in one meeting, this could be staggered over regular monthly meetings of the management team.

This requirement is unlikely to change in the revision to ISO/TS16949, but requirements will also include understanding the risks and opportunities in each process that could affect meeting the desired results, taking action to address risk, and maximize opportunities.

Question:

I know the final version of the revised ISO/TS16949 will not be issued until later in the year, but is there any indication what additional requirements the revision will include?

Answer from Quality Partner:

The first thing is that the requirements of ISO/TS16949: 2009 will be restructured to the ISO9001: 2015 structure. The focus on the process approach to Quality Management will remain, but will incorporate the

focus on risk based thinking. Secondly one of the objectives in the revision process is to try to use this opportunity to incorporate in the requirements some of the common OEM customer specific requirements. Below are examples of some of the potential changes:

- Need to consider the needs of interested parties, not just the customer
- More focus on understanding product safety requirements and managing them in the product realization processes
- More requirements related to effective development and implementation of the contingency plan
- Need to ensure all those involved in communicating with external customers have the appropriate competency, including customer specified training where required (e.g. Capacity planning, scheduling, design skills etc.)
- More stringent requirements related to supplier selection and monitoring, especially understanding risks in the supply chain process (e.g. Single source supply)
- Strengthening of the requirements for maintenance, incorporating the concepts of Total Productive Maintenance (TPM)
- More stringent requirements related to the use of rework, including understanding risks before rework commences.
- Promoting the use of globally recognized best practice tools in the internal audit process (e.g. VDA 6.3, MMOG-LE etc.
- More focus on effective use of error proofing and verification of error proofing devices
- New requirements related to warranty management

It is likely that organizations will only have two years to make the transition to the revised requirements, so start planning now!

Whereas many training providers will offer 'off the shelf' open training, Quality Partner, utilizing its global network of partners, offers tailored in-house training to understand the new requirements and implementation support to help effectively meet the requirements. As well as having some of the most experienced ISO/TS16949 experts, Quality Partner also has experts in Total Productive Maintenance (TPM) and MMOG-LE to meet all needs an organization may identify in addressing the revised requirements.

Future editions of this newsletter will give further updates and contain more detailed requirements on the revised requirements.

For more information contact enquiries@qualitypartner.co.uk or call +44 (0)7341845930