Quality Partner Newsletter July 2020

Issue date: August 2020

Welcome to the nineteenth edition of the Quality Partner newsletter. The newsletter is designed to keep readers up to date with developments in Quality Management Systems.

This issue focuses on:

- The IATF Covid response simply explained
- Effective remote auditing techniques
- Focus area for IATF 16949 audits after Covid 19 Pandemic disruption

If you have any questions or topics for future editions, please feel free to mail to: paul.hardiman@qualitypartner.co.uk

Since the newsletter in April 2020, who again would have predicted the massive impact that Covid 19 would have on all our lives, and the devastating effect on the automotive supply chain.

As I mentioned in the last newsletter, we can either be pessimists, and get depressed about the current situation, or we can see this as an opportunity for us as individuals, and the organizations we work for to learn new skills and explore new markets and opportunities

Remember the strapline:

“Go to bed with one extra piece of learning/knowledge you did not have when you woke up!”

Many of you took the opportunity to improve your knowledge on the automotive core tools by watching, using the free links, the 11 short videos and taking the online exams.

If any of you missed the opportunity and would like to view the video series free of charge please contact me at paul.hardiman@qualitypartner.co.uk

At Quality Partner, we have responded to the demand by scheduling a range of online training workshops, in association with my friends in Quality Partner Thailand. Full details are included in this newsletter, I hope you can join!

For More Information Visit www.qualitypartner.co.uk

Author: Paul Hardiman

qualitypartner
delivering quality as standard

Covid 19 IATF response 4th edition

Many of you will be aware that IATF have issued instructions to the recognized certification bodies and IATF certified organizations on how to manage the disruptions in audit schedules caused by the Covid 19 pandemic.

On the 17th July the 4th revision of the document was published in the IATF Global Oversight website, https://www.iatfglobaloversight.org/

Let us try to simply explain the key changes in the 4th revision:

- **Scheduling IATF 16949 audits**

In the IATF Covid-19 Response, it makes it clear that if safe to do so and allowed by the relevant country and organization rules and regulations, IATF 16949 audits should be undertaken as per the original planned schedule.

In the case of disruption caused by the Covid 19 Pandemic, the following applies:

- Surveillance audits

  The IATF Covid-19 response allows a surveillance audit to be undertaken up to 90 days later than the originally planned audit without the IATF 16949 certificate being suspended. If the audit still cannot be undertaken due to the Covid 19 pandemic by the end of this 90-day extension (named 1st extension), the client certificate is placed in suspension by the certification body. (As defined in the IATF 16949 scheme rules a certificate in suspension is still valid and there is no requirement to inform customers of the suspension status)

  There is then another opportunity for the planned surveillance audit to take place within 90 days of the certificate suspension (named 2nd extension).

  Hopefully this extra 180 days (total of 1st and 2nd extension) will give enough flexibility to make sure planned IATF 16949 surveillance audits can take place.

  If not, IATF have introduced the possibility for certification bodies to undertake a remote monitoring activity.

- IATF Monitoring

  Firstly, IATF monitoring is only applicable when a surveillance audit cannot be undertaken within the time window outlined above due to the Covid 19 pandemic.

During a monitoring activity, minimum of 1 day, the auditor will verify, using remote communication tools, that the organization quality management system (QMS) is still working effectively to meet customer and interested party expectations. This will include reviewing customer scorecards, internal performance data, and changes made to the QMS due to the pandemic.

The time window that monitoring can take place is from 30 days before the end of the 2nd extension outlined above, to 60 days after the end of the 2nd extension. This effectively gives a 90- day time window for IATF monitoring activity.

There are two possible outcomes of the monitoring event, namely high or low risk (definitions are in the IATF Covid-19 response document).

If low risk, the IATF 16949 Monitoring can replace the original surveillance manufacturing site audit. Time will be added to the next audit (if the next audit is a surveillance audit, the onsite audit days should be equivalent to recertification audit days, if the next audit is a recertification audit, the onsite audit days should be equivalent to stage 2 audit days (defined in IATF rules table 5.2)).

If high risk is identified at the first monitoring event, following up monitoring activities can be performed in the 90-day monitoring time window, giving the client time to define the improvement actions needed to move from high to low risk.

If low risk cannot be achieved in the monitoring period, the IATF certificate will be withdrawn.

- Recertification audits

If, due to the Covid 19 Pandemic the planned recertification audit cannot be undertaken in accordance with the originally planned schedule, IATF have introduced a six-month extension to all certificates (This change has been made in the IATF database but the physical certificates will not be updated) to allow flexibility in time window for undertaking the audit. Effectively this means the recertification audit can be planned up to 180 days beyond the originally planned date. However, the certification body needs to ensure the scheduling allows time for the organization to take the necessary actions to address any nonconformities before the expiry of the certificate.

If the recertification audit cannot be undertaken in the extended time window, the certificate will be withdrawn. IATF monitoring is not applicable to recertification audits.

- Initial IATF 16949 audits

  It is likely the number of organizations entering the IATF scheme with an initial audit (stage 1 and stage 2) will be dramatically reduced. If an organization had a stage 1 audit and if, because of the Covid 19 pandemic, the stage 2 audit cannot be undertaken within 90 days of the stage 1 readiness decision, IATF are allowing another 90 day window for the stage 2 audit to take place.

- **Addressing nonconformities**

In simple terms, if an organization has nonconformities raised during an IATF 16949 audit, and the nonconformities cannot be closed within the normal nonconformity management time window, due to the Covid 19 Pandemic (a total of 90 days for the organization to take action to address the nonconformity and the certification body to verify as closed (either on site or remotely)), IATF is allowing an additional 90 days for the completion of the nonconformity management process.

If due to the pandemic, the organization still cannot close the nonconformity in the above time, or the third-party auditor cannot conduct the required verification activity, IATF have given the option to use “100% resolved” status. To achieve 100% resolved for a nonconformity, an organization, at minimum, must take correction, complete root cause analysis, and define a detailed corrective action plan, and submit to the certification body for approval.

Summary

In summary, IATF are trying to introduce flexibility in timing of audits and management of nonconformities, but at the same time maintain the integrity of the scheme. I am sure there will be more revisions as the full scale of the Covid 19 Pandemic become apparent.

The 4th revision of the IATF Covid response introduces some more flexibility is the scheduling of audits and IATF monitoring activities, but still does not allow any form of remote auditing. I hope that consideration will be given in the 5th edition to allow for remote auditing of remote support functions, that are not involved in handling the product (for example sales, purchasing, IT, product design and other “office” based activities). Watch this space!

Maintaining an IATF 16949 internal audit programme during the Covid 19 Pandemic

One of the challenges an organization faces during the disruption of the Covid 19 Pandemic is maintaining an internal audit programme. In the IATF Covid-19 response, the frequently asked question and answer 3 states:

Question:
During this crisis, the conducting of internal system audits by certified organizations in accordance with the requirements of the IATF 16949 Standard (i.e. sections 9.2 and the subsequent sections) may be restricted or limited. How shall compliance with these requirements be justified and documented?

Answer:
E*ven during this crisis, the basic requirements outlined in section 9.2.2.1 are still applicable. The requirements specify, for example, “The audit programme shall be prioritized based upon risk, internal and external performance trends, and criticality of the process(es).” Therefore, this requirement already covers the risk associated with conducting internal audits. In this crisis, the risk for the safety and health of internal auditors and auditees is at an even higher priority than during “normal” times. The organization shall*

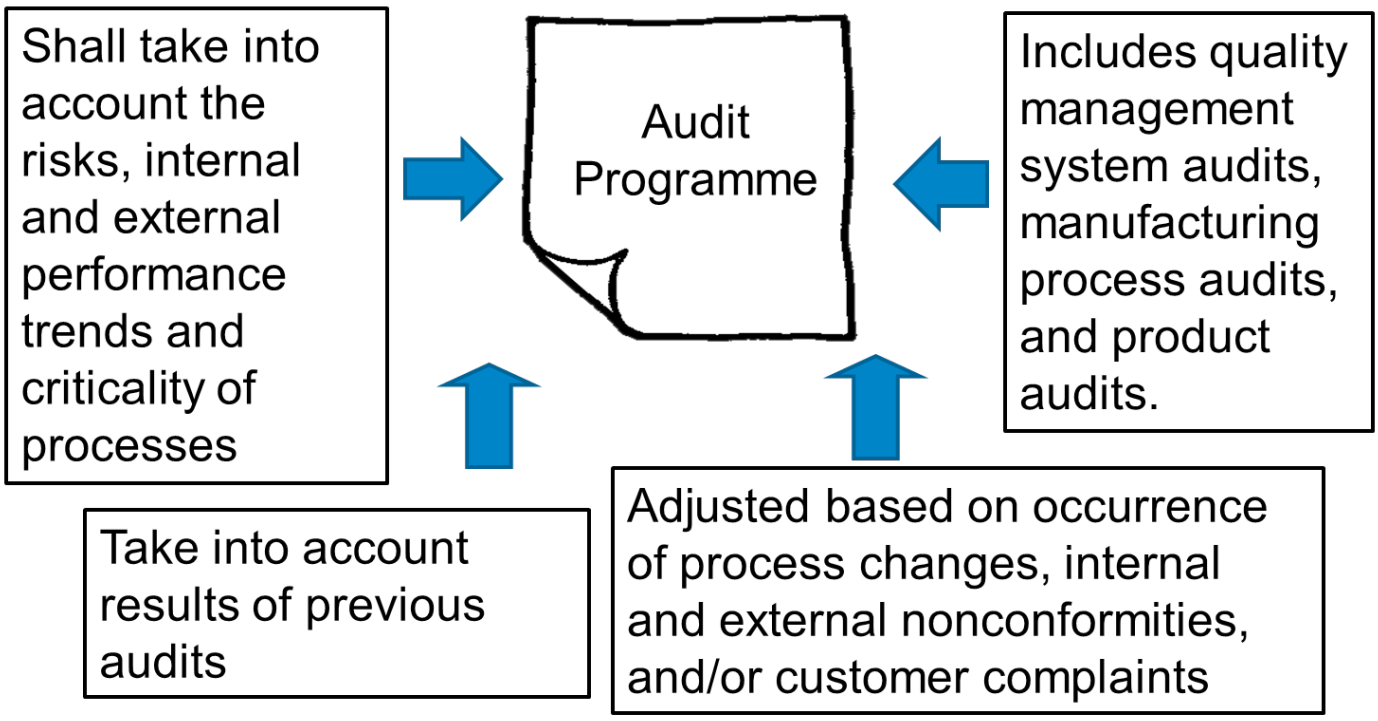
determine the risk associated with physical on-site audits and potentially consider other auditing methods (e.g. remote audits), providing the organization is able to demonstrate the effectiveness of these auditing methods and associated risk assessments.

I believe, even before the Covid 19 Pandemic, that undertaking remote audits, for both internal and second party audits, was allowed. In ISO9001: 2015, which forms the foundation of IATF 16949, it refers to ISO19011. In ISO19011: 2018, "Guidelines for auditing management systems" both onsite and remote auditing activity are covered.

However, before considering the possibility of remote audits, the associated risks need to be fully understood and managed.

- **Internal Audit programme**

IATF 16949 requirement 9.2.2.1 adds requirements relating to developing and maintaining an audit programme. The IATF requirements state that all QMS processes, and all manufacturing processes on all shifts, are audited at least once in a three-year cycle. However, this is the minimum requirement. In developing the audit programme the following points need to be considered:



It is likely the Covid 19 pandemic may have changed the way some QMS processes operate, and the related process risks could have also significantly changed. Based on this, and any internal or external performance issues, the internal audit programme should be reviewed, and where necessary be updated.

The next decision is whether the planned audits can be safely undertaken onsite, observing any legal or organization safety rules on safe distancing, or remotely.

To decide on whether onsite or remote audits are possible, some example prompt questions are shown below:

1. Are people involved in the process (including process owner) working on site?
2. If yes, are there any restrictions to enter the area where the process takes place?
3. If yes, what are the restrictions? Is it permitted/ safe to enter the area to undertake the audit?
4. If safe, what are the PPE requirements needed in the area and any safety protocols to be observed (e.g. safe distancing)
5. If answer to question 1 is no, are the people still involved in operating the process remotely?
6. If answer to question 5 is yes, will they have access to all the relevant documentation needed to undertake an audit of their process remotely?
7. Based on the answer to question 6, and considering the communication technology available, can an effective remote audit be undertaken?
8. If answer 7 is yes, who would need to be involved in the remote audit?

Once it is decided a remote audit is feasible, the auditor needs to start the planning activity. From my experience the success of a remote audit depends on effective planning.

- **Remote audit planning**

Once it had been decided a remote audit is feasible, the next task for the auditor is to plan and prepare for the audit.

This can be broken down into two parts, namely the communication planning and the technical planning.

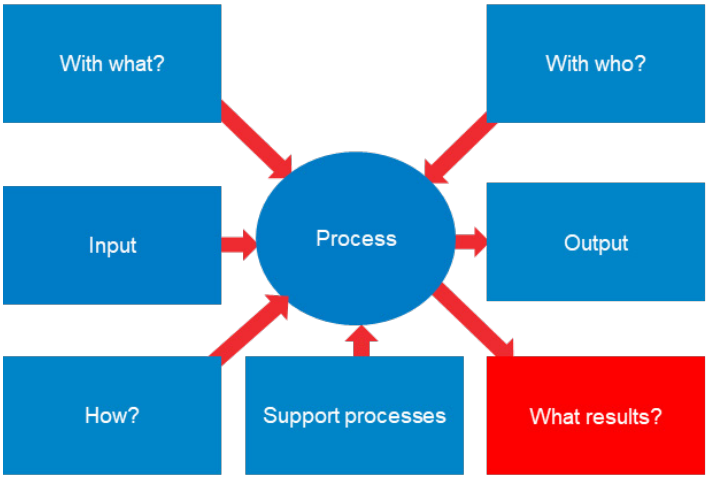
The communication planning needs to include:

- Who needs to be involved in the audit?
- What technology is going to be used for the remote audit (e.g. Teams, Zoom, Go To Meeting etc.)?
- How much time is needed for the audit? From my experience, a rule of thumb is to double the time that a “normal” onsite audit would take. Also, doing remote audits is very tiring for both the auditor and auditee, so I would recommend planning shorter days (maybe 4-hour sessions per day with regular breaks)

For the technical planning of the audit, this needs to include:

- What is going to be the scope of the audit? (which process, sub-process to be audited)
- What is going to be the audit criteria? (e.g. ISO9001, IATF 16949, CSR’s, procedures etc.)
- What is the objective of the audit? (e.g. to verify the QMS is still effective during any Covid 19 Pandemic disruption)
- What information is needed for effective audit planning? In my experience planning is the key ingredient in undertaking an effective remote audit. In advance of the audit, based on the audit scope, the auditor should request from the process owner information that may include:

    - Quality Objectives/targets
    - Customer scorecards and performance data
    - Internal performance data
    - Relevant documented processes and procedures
    - Contingency plan
    - Management review results
    - Previous audit results



Time should be spent on reviewing the information to develop a turtle diagram and/or audit questions, focused on the information provided by the auditee. This preparation will mean there is less need to spend time looking at the computer screen trying to read the information, resulting in effective use of everybody's time on focusing on the areas of highest process risk.

Once both these aspects of the audit preparation are complete the audit agenda can be developed and communicated to the process owner and any relevant auditees.

- **Undertaking the remote audit**

Even though the audit is being undertaken remotely, there is still the need for the auditor to do allow time for introductions and confirm the audit agenda, timings, scope, criteria, and objectives.

Then undertaking the remote audit is like any "normal" audit, where the auditor should focus on performance and the areas of highest risk. It should be ensured that the audit is not just a "chat", but objective evidence is sought and recorded from the process owner, using shared screen technology. It is also important for the auditor to be in control, for example in not letting the auditees select the audit samples for review.

Regular breaks should be taken, and at the conclusion of the audit the auditor should verbally summarize any audit findings, before preparing the audit report. The audit report should contain details of the process (s) audited, the evidence reviewed, any nonconformities, any opportunities for improvement and the audit conclusion (including the need for any follow up audit).

- **Conclusion**

In my view, any quality management system audit can be undertaken effectively remotely, if the relevant technology is available, the auditor takes time doing effective audit planning, and more time is planned for the actual audit activity.

The same applies to second party (audits of suppliers). Again, I believe this is feasible, but it depends on the proposed scope and objectives of the audit. For example, it may be feasible to audit a supplier's response to the disruption caused by the Covid 19 Pandemic remotely including any updating of their QMS.

If there are issues with the supplier's performance related to quality or delivery, the corrective action process could be audited remotely. However, it would not be possible to do a detailed manufacturing process audit (unless camera technology was available to "walk the process").

Quality Partner in UK, in association with Quality Partner Thailand, have been running several online workshops, including a course on remote auditing.

All the courses are priced at an amazing value of £40+VAT (or $50 US), which is fully inclusive of all course materials (course slides, handouts, case study materials and course certificate).

You can find full details of the next remote auditing workshop planned for the 27-28th August 2020 by visiting:

https://www.qualitypartner.org/en/online-course/undertaking-effective-remote-iatf16949-internal-and-second-party-audits-27-28-aug-2020/

Focus areas in IATF audit after any Covid 19 Pandemic disruption

Several people have asked me in the last couple of months on what will be the focus areas in IATF 16949 third party audit after any Covid 19 Pandemic disruption.

My ideas are below but would welcome any feedback on these and anything you think I have missed!

1. Top Management involvement

Many of us will know that in many IATF 16949 certified organizations Top Management are not really involved in the management of the quality management system and do not use it effectively to manage the business activities. This is an ideal opportunity for third party auditors to put management commitment to the test!

IATF 16949 clause 9.3.1.1 states:

"Management review shall be conducted at least annually. The frequency of management review(s) shall be increased based on risk to compliance with customer requirements resulting from internal or external changes impacting the quality management system and performance-related issues."

I cannot see that there would be any IATF certified organization, anywhere in the world, that has not been affected in some way by the Covid 19 Pandemic. So how would an annual management review meet the above requirement?

I am sure third-party auditors will be looking at this requirement, and the involvement of Top Management, through the audit of the management review process. Evidence of a dynamic management review process could include changing strategic direction, adjusting targets for the defined quality objective, reviewing customer scorecards, reviewing any production start-up issues, and analyzing the effectiveness of any plant layout changes due to the Covid 19 Pandemic.

2. Contingency planning

I am sure third-party auditors will be looking for evidence of the effectiveness of the contingency plan during any production disruption, and the effect any disruption had on delivery performance to customers.

IATF requirement 6.1.2.3 Contingency planning states:

The organization shall:

“a) identify and evaluate internal and **external risks** to all manufacturing processes and infrastructure equipment essential to maintain production output and to ensure that customer requirements are met;
I do not think, prior to the Covid 19 Pandemic, I have seen any contingency plan that covered such a global devastating situation.

The requirement also defines an organization shall:

c) (including SI 3) “prepare contingency plans for continuity of supply in the event of any of the following: key equipment failures (also see Section 8.5.6.1.1); **interruption from externally provided products, processes, and services;** recurring natural disasters; fire; utility interruptions; cyber-attacks on information technology systems; **labour shortages**; or infrastructure disruptions;”

The Covid 19 pandemic has not only disrupted certified IATF 16949 organizations (for example with labour shortages), but also the supply chain, with the challenges not only with suppliers being able to manufacture products and materials, but be able to ship them to their customers.

Third party auditors will be looking for review, and update where required, of the contingency plan, especially if there has been any disruption caused to the customer related to supply issues. The IATF requirement makes it clear this should be done with a cross functional team, involving Top Management.

3. Roles, responsibilities, and authorities

Unfortunately, due to the Covid 19 Pandemic, many organizations have been forced to reduce employee numbers and make organizational changes to survive. Auditors will focus on how job roles, responsibilities and authorities have been reviewed and if necessary updated.

In addition to the ISO9001: 2015 requirement 5.3. IATF 16949 adds:

“5.3.1 Organizational roles, responsibilities, and authorities — supplemental

Top management shall assign personnel with the responsibility and authority to ensure that customer requirements are met….”

As well as defining any changed job roles, an organization needs to ensure that people are competent to perform any modified roles, and that any training needs are documented, planned, and actioned.

4. Restart of production

In the 2016 publication of IATF 16949 a new requirement was introduced, namely:

8.5.1.4 Verification after shutdown

“The organization shall define and implement the necessary actions to ensure product compliance with requirements after a planned or unplanned production shutdown period.”

Many organizations had/have enforced shutdowns because of the Covid 19 Pandemic. Auditors will be focusing on how effective the restart of production was, by looking at internal and external performance results.

5. Plant layout

The IATF requirement 7.1.3.1 Plant, facility, and equipment planning states:

"The organization shall use a multidisciplinary approach including risk identification and risk mitigation methods for developing and improving plant, facility, and equipment plans."

The Covid 19 Pandemic has forced many organizations to change plant layout to accommodate for safe distancing rules and operator safety. Auditors will be focusing on how changes in layout have been controlled and, where necessary, if customers have been informed of such changes, especially if they affect the product and process approval requirements.

6. Standardised work

The IATF requirement states:

8.5.1.2 Standardised work — operator instructions and visual standards

"The organization shall ensure that standardised work documents are:

a) communicated to and understood by the employees who are responsible for performing the work;
b) legible;
c) presented in the language(s) understood by the personnel responsible to follow them;
d) accessible for use at the designated work area(s).

*The standardised work documents shall also include rules for **operator safety**."*

Auditors will be focusing on the process of updating, and validating operator understanding of, standardized work, especially if changed as a result of the Covid 19 Pandemic. This could include changes made in workplace/cell layout or changed work activities due to Covid 19.

7. Internal audits

Auditors will focus on whether the internal audit programme has been reviewed, considering QMS changes made during any Covid 19 disruption, and updated as necessary, including addition of any remote audits, based on a structured risk analysis.

8. Calibration

A common focus area of IATF 16949 audits is the organizations management of calibration. The Covid 19 Pandemic may have had an effect on the calibration process, especially if external calibration providers cannot get to site because of the Covid 19 Pandemic.

In these cases, the 3rd party auditor will be looking for evidence of a risk analysis by the organization, that may include reviewing previous calibration results and the time the instrument has not been used (for example during a plant shutdown). If the risk is deemed as low, the organization may decide to extend the calibration frequency, with maybe introducing interim internal verification checks (Bias, linearity, and stability), until the normal external calibration service can be resumed.

The same requirements would apply, even if the filter was not fitted to the engine, but was supplied with the engine, under the supply contract from the customer.

9. Design and development (Product and/or process)

Before the Covid 19 Pandemic, many organizations would have been working on new product introductions to meet customer defined timing requirements. Auditors will focus on the organization's communication with customers on any changed timing requirements, and how changes have been agreed and factored into any relevant project plans.

10. Supplier management

Due to the Covid 19 Pandemic, organization's may have had to make changes in supply sources, maybe forced to seek and use new suppliers. Auditors will focus on how suppliers were selected (see IATF requirement 8.4.1.2 Supplier selection process) and how supplier performance from existing suppliers is being monitored, focused on areas of the highest potential risk.

Summary

The key evidence that 3rd party auditors will look for is that the QMS is dynamic and is being reviewed, updated, and used to manage the organizations processes to meet customer and interested party needs.

Additional online training courses planned for August and September 2020

Below are details of the upcoming online training courses delivered in partnership between Quality Partner UK and Quality Partner Thailand.

All are priced at an amazing low price of $50 (£40+VAT) per delegate, fully inclusive of all course materials and course certificates. Places can be booked online through the links below or by contacted paul.hardiman@qualitypartner.co.uk

Effective auditing of MSA and SPC utilizing the process approach incorporating risk-based thinking

3.5-hour workshop: 13th August, 14.00-17.30 Thailand time

For IATF 16949, 3rd party auditors are having to do mandatory training and examinations to improve the auditing of the automotive core tools.

This online workshop is focused on giving experienced internal and second party auditors the opportunity to improve their auditing skills related to MSA and SPC.

The workshop will include practical case studies and online audit role plays to ensure delegate engagement and learning.

https://www.qualitypartner.org/en/online-course/effective-auditing-of-msa-and-spc-utilising-the-process-approach-incorporating-risk-based-thinking-13-aug-2020/

Effective auditing of PFMEA and Control plan utilizing the process approach incorporating risk-based thinking

3.5-hour workshop: 24th August, 14.00 Thailand time

For IATF 16949, 3rd party auditors are having to do mandatory training and examinations to improve the auditing of the automotive core tools.

This online workshop is focused on giving experienced internal and second party auditors the opportunity to improve their auditing skills related to FMEA and control plan.

The workshop will include practical case studies and online audit role plays to ensure delegate engagement and learning.

https://www.qualitypartner.org/en/online-course/effective-auditing-of-process-fmea-and-control-plans-utilising-the-process-approach-incorporating-risk-based-thinking-24-aug-2020/

Introduction to MMOG-LE 5th edition

3.5-hour workshop: 4th September 2020 2.00pm-5.30pm Thailand time

Global Materials Management Operations Guidelines/Logistics Evaluation (MMOG/LE) is a self-assessment and continuous improvement tool that provides the means to enhance materials management efficiency and accuracy while reducing costs from errors and waste. MMOG/LE is a global standard of industry best practice for supply chain management processes.

Its purpose is to establish a common definition of supply chain management best practice to facilitate efficient and effective physical and information flows between internal and external partners. Compliance to MMOG-LE is a requirement of several vehicle manufacturers and suppliers in the automotive supply chain.

This workshop is designed to introduce delegates to the recently published 5th edition of MMOG-LE and will include delegate exercises and ample time for discussion. The workshop is applicable to people working in supply chain processes, internal auditors and Management looking to improve the efficiency of

supply chain processes.

https://www.qualitypartner.org/en/online-course/introduction-to-mmog-le-5th-edition-4-sep-2020/

If the dates for the above courses are not suitable, or if you would like to discuss the possibility running any of the online courses in-house please contact paul.hardiman@qualitypartner.co.uk