

Discussion on ISO/TS16949 Requirements



The following section of the newsletter is intended to stimulate discussion on the practical application of ISO/TS16949. Certification bodies and organisations in the automotive supply chain are invited to provide questions for future newsletters

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If you have any comments on the answers given below please do not hesitate to contact paul.hardiman@industryforum.co.uk

An organisation states in their quality system that they have an annual management review. Is this acceptable?

The first thing we need to consider is the requirement 5.6.1:

“Top Management shall review the organisation’s quality management at planned intervals.....”

So how can auditor make a decision of when the planned intervals established by an organisation is acceptable?

Firstly any customer specific requirements need to be taken into account. For example the Ford ISO/TS16949 customer specific requirement, 4.7, states:

“The organization management shall hold monthly QOS (Quality operating system) performance meetings.....”

They also add a note:

“The management review need not be held as one meeting, but may be covered in a series of meetings, covering each of the metrics monthly”.

The second thing that needs to take into account is the performance of the Quality Management System and specifically the performance against the quality objectives.

ISO/TS16949 5.6.1.1 states:

“Part of the management review shall be the monitoring of quality objectives and the regular reporting and evaluation of the cost of poor quality.”

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If an organisation states they have an annual review, they are therefore saying they only review performance annually which in most companies is not reality.

The problem is often the definition of the management review process in the organisation's quality management system. Whereas many organisations have more regular management meetings, these meetings are often not included in the management review process. In addition, Managers often see the formal annual management review meeting as a waste of time as the topics covered have already been covered in other meetings.

A possible solution is for organisations to take the opportunity to review the agenda and outputs of each meeting held and then relate this to the requirements defined in ISO/TS16949 5.6.2: Management Review input. It may then be possible to demonstrate that all the requirements are met within the existing meeting structure, rather than as a standalone annual Management review

Conclusion: In a "perfect" organisation, where all objectives for effectiveness and efficiency are met, and where there are no customer specific requirements, an annual review may be justified. In other cases a more frequent review would be needed to fully meet the intent of the requirement.

An organisation states in their quality system that layout inspection is only undertaken where specified by the customer. Is this acceptable?

ISO/TS16949, Clause 8.2.4.1 defines the requirement

"A layout inspection and functional verification to applicable customer engineering material and performance standards shall be performed for each product as specific in the control plans. Results shall be available for customer review"

And the note adds "Layout inspection is the complete measurement of all product dimensions shown in the design records"

To judge acceptability firstly we need to take into account customer specific requirements. Some customer specifics state they require an annual layout inspection.

If there is no customer specific requirements an organisation needs to decide on a suitable frequency. To do this performance and risk needs to be taken into account. For a product with historic concerns, the frequency would be more often (maybe annual) than for a product with no concerns (maybe every 3 to 5 years). As performance will change over time, an organisation may elect have an annual meeting to review the results of any layout inspections undertaken and plan the next cycle.

The control plan would need to be updated with the appropriate frequency established.

Conclusion: Even if there are no customer specific requirements for layout inspection, the requirement still needs to be addressed by the organisation. However the frequency is not dictated by the requirement, and as such, based on performance, the frequency may be longer than one year.

An organisation provides evidence that it undertakes a programme of internal audits. They demonstrate that all the requirements of ISO/ TS16949 are covered in an annual cycle by undertaking audits of each of its processes utilising the process approach. They have a separate programme of product audits. They do not have a separate programme of system audits. Is this acceptable?

ISO/TS16949 requirement 8.2.2 states that

“the organisation shall conduct internal audits at planned intervals to determine if the quality management system conforms to planned arrangements.... and is effectively implemented and maintained.”

According to ISO/TS16949 requirement 4.1, a quality management system should be based on the organisation processes. Therefore is an organisation audits each of the processes of the quality management system (product realisation and support processes) by inference they are auditing the quality management system, and hence undertaking system audits.

To meet the additional ISO/TS16949 requirements 8.2.2.1 and 8.2.2.2, any process based audits of the system audits would need to demonstrate they ensure the processes comply with ISO/TS16949 and any Customer Specific Requirements, and that the audits verify not only compliance, but effectiveness of processes.

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Regarding product audits (8.2.2.3), these should be planned, undertaken by competent auditors, and records maintained.

Conclusion: An organisation needs to demonstrate their internal audit process addresses the requirements for system, process and product audits, but these do not have to be through separate programmes, for example system and process audits addressed together by undertaking audits of all the Quality Management System processes, and hence addressing all the system requirements.

An organisation states that their quality system documentation and records are maintained in electronic format, with no hard copies maintained anywhere in their facility. Is this acceptable?

ISO/TS16949 requirement 4.2.1, note 3 states

“the documentation can be in any form or type of media”

To audit effectiveness an auditor should question how the electronic documentation is controlled, who has the authority to revise/amend documentation, how do people throughout the organisation have access to the system documentation and how they are informed of any amendments.

Also the system back up should be questioned, if the electronic system fails, what is the contingency plan to allow access to the quality management system documentation.

The requirement 7.5.1.2 states Work Instructions:

“shall be available at the work station”

However this does not state hard copy. Organisations may elect to have terminals for electronic access at each workstation to address the requirement.

Conclusion: Yes, it is acceptable, subject to the the above points being addressed.