

## Auditing the process function

**ISO/TS 16949:2002 and ISO 9001:2000 require organizations to prove that their processes are measured, monitored, and improved.**

ISO 9001:2000's emphasis on both processes and customers is the chief difference between the standard's 1994 format and the current version. In my latest book, *The ISO/TS 16949:2002 Auditor Handbook: Process-Approach Auditing for the Automotive Industry*, I discuss process auditing and customer focus as it applies to ISO/TS 16949:2002. This article is based on concepts from chapter 4 of that book, which will be published later this year by Paton Professional.

In preparation for conducting an internal, second, or third-party audit, an auditor should conduct a readiness review before proceeding with the onsite audit.

The process-focus section of the readiness review includes the following five steps:

1. Study the scope.
2. Understand the sequence and interaction of the processes.
3. Conduct the document review.
4. Confirm that a quality manual is available at each site.
5. Confirm that a list of internal auditors is available.

The first two steps are arguably the most critical when auditing for ISO 9001 and ISO/TS 16949:2002 compliance. Organizations have had six years to accustom themselves to the changes in ISO 9001:2000, yet despite this, the same mistakes are being repeated over and over by both implementers and auditors. I hope this article sheds some light on some important issues that affect scope, interaction, process orientation, and process management.

Simply put, the issues of scope include ensuring that all relevant entities of an organization are included, and that the organization's processes explain the interaction between the entities. These processes also must be measured, monitored, and improved. Process focus and management offer probably the most value for organizations that implement ISO 9001:2000, so if these processes aren't developed and audited correctly, the organizations stand to lose both financially and competitively.

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## Understanding the audit scope

When auditing an organization, the auditor should locate the manufacturing site, design location, sales, warehouses, and purchasing entities. In ISO/TS 16949:2002 the manufacturing site is referred to as the "site," and the supporting locations are defined as "remote locations." There are many important rules for auditors involved in automotive auditing, including the need to audit the supporting functions before they audit the site.

When studying the interactions between the manufacturing site and its support locations, it's evident that, in many cases, the process starts in the supporting function and then enters the site. Therefore, it's important for the auditor to plan the processes and the interfaces during the readiness review.

Organizations tend to draw artificial boundaries between what they do and don't want audited. ISO/TS 16949:2002's clause 1.2, Application, sheds some light on how an auditor should evaluate the audit scope. The ISO 9001:2000 portion requires that when exclusions are made, they shouldn't affect the "organization's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements." In other words, organizations can't make exclusions if these would affect either regulatory or customer requirements.

ISO/TS 16949:2002 goes on to specify that an exclusion can be made only for clause 7.3, Product design and development. But what if something else needs to be excluded? For example, what if the organization doesn't have customer-supplied product? The International Automotive Task Force (IATF) Guidance to ISO/TS 16949:2002 advises that the organization is required to have a process for customer-supplied product, and that it should use the process if and when it gets customer-supplied product.

The auditor must check the following three steps when studying the scope:

1. Identify all of the entities in the organization that service the customer. Identify the site, supporting locations, and outsourced processes. Use the organizational chart and ask enough questions to determine how the organization works and to identify the locations of all related functions.
2. Study the quality manual and the process map or equivalent to determine if all the processes of the organizational entities, including outsourced processes, are included in the scope.
3. Identify audit responsibilities for all the entities. Who will audit the entities that are relevant to the organization?

## Process orientation and interaction

The auditor should study the organization's process map or equivalent during the audit. Is this document location-specific, and does it explain the processes being audited? As previously mentioned, many processes connect between site and remote locations. Business planning, objectives deployment, management reviews, new product development, purchasing, and sales are a few processes that have the potential of crossing functional and geographical areas. Sample the process documents. Are the interfaces

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of the processes clearly identified between locations, or do the documents stop within the four walls of the site or support function?

It should be evident to most auditors when an organization has repackaged ISO 9001:1994 and/or QS-9000 procedures as processes. Processes are not clauses. Also, processes that start and stop within the four walls of a site or supporting function aren't process-focused. These are typical failures I've seen when auditing.

Examine your process maps. Do you see any problems with these? The auditor should be aware of the distinction between a true a process approach vs. an elemental, departmental, or functional approach to developing processes. Processes identified by the organization shouldn't be restatements of the ISO/TS 16949:2002 clauses, and they shouldn't be departmental or functional processes, either.

### Constructing process maps

Check to make sure the organization has a good grasp of what a process map is. Do the maps exhibit the following characteristics?

- Process maps should be simple and at the same time descriptive enough to show the sequence and interaction.
- The processes included on the map should be meta-processes from which flow several lower-level processes typically documented in level two procedures.
- Is there a process map that shows how all of the entities link together and how the overall processes link corporate, sales, design, manufacturing, assembly, and the warehouse?
- Does the process map of the entity being audited show the sequence and interaction of the processes at that site or entity?
- Study the links or process interfaces for multiple processes between the site and remote location as well as within the entity being audited. Do the inputs and outputs match? Does the process interface make sense relative to the process being studied?

This is the "quality paradigm" of professionals who've worked with standards since the days of Ford's Q-101 or General Motors' Targets for Excellence. Since the 1980s organizations have followed procedures developed by quality professionals and that are based on the requirements of various standards. Because of this, it's difficult for implementers or auditors to see beyond the requirements of the standards to the actual processes that make the organization function.

The auditor should check the following for process orientation and interaction:

- Do the organization and auditor understand the process map and the processes in the organization?
- Do the organization and auditor understand how the processes work between the site and its support functions? Are the interfaces well understood?

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- Does the organization know all its outsourced processes? The auditor should have confirmed control of this during the documentation review.
- Is the sequence of processes and their interaction (including the interfaces) working well for the organization?
- Are the processes measured, monitored, and improved?

### Process management

In both ISO 9001:2000 and ISO/TS 16949:2002, clause 4.1, General requirements, requires that processes are identified, that their sequence and interaction are explained, and that they're measured, monitored, and improved by the organization. If the processes explained in the earlier section (i.e., those connecting the entities in the organization and that are global in nature) are measured and monitored, they can be a great source of information about how the organization works. Information to be gleaned from these processes include:

- The hit rate of sales
- Lead time of new product development
- Customer satisfaction
- Overall delivery and quality measures
- Manufacturing lead time

Clearly, these measures are of interest to top management, and this is why clause 5.6, Management review, expects top management to review process performance. ISO/TS 16949:2002's clause 5.1.1, Process efficiency, requires that top management "shall review the product realization process and the support processes to assure their effectiveness and efficiency." How is this taking place in the organization? Study the process performance data to determine the process performance.

Clause 5.1.1 also requires top management to ascertain whether processes are effective and efficient. The effectiveness of a process requires that it yield results. However, these could be achieved in an inefficient manner that uses more resources than required. Thus, a process should not only yield planned results but also be efficient in the way it does so.

ISO 9001:1994 doesn't mandate process owners, but it's evident in both ISO 9001:2000 and ISO/TS 16949:2002 that if processes are to be managed, there must be a designated process owner. In other words, there must be someone in the organization who's responsible for defining, measuring, monitoring, and improving the different processes.

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### Process characteristics

ISO/TS 16949:2002 has defined process characteristics that can serve as guidance for both ISO 9001 and ISO/TS 16949:2002 auditors. They include the following:

1. A process owner exists.
2. The process is defined.
3. The process is documented.
4. The links of the process are established.
5. The process is monitored and improved.
6. Records are maintained.

Top management often views implementing and auditing ISO/TS 16949 and ISO 9001 as "necessary evils" and overlooks the standards' relevance and importance. One value-added area mandated in both is the process focus, and the auditor should ensure that the organization has complied with this important requirement. Becoming process-focused starts with a scope audit to determine if all the entities are included and the organization's processes connect them. The auditor should question whether the organization has fallen into the trap of functional- or clause-based process maps and should also evaluate whether the processes are measured, monitored, and improved. The organization should have a document that explains how this is being done. Also, top management should be reviewing the process performance during the management reviews.

Implementing and auditing quality management systems that are process-focused will provide value to the organization and is a fundamental building block of ISO 9001:2000 and ISO/TS 16949:2002.

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