WHAT EVERY EMPLOYEE NEEDS TO KNOW ABOUT ISO/TS 16949:2002

A Pocket Guide to the Basics

First Edition

New requirements and changes from QS-9000
are clearly identified through the use of blue text.

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THE ISO/TS 16949 STANDARD

THE DOCUMENTATION SYSTEM

THE REQUIREMENTS OF ISO/TS 16949

THE AUDIT PROCESS

QUICK REFERENCE GUIDES

ADDITIONAL MATERIALS AND TRAINING

THE
ISO / TS 16949
STANDARD

WHAT EXACTLY IS ISO/TS 16949?

ISO/TS 16949:2002 is an international standard and "technical specification" containing requirements for establishing and maintaining a **quality management system** for the design and development, production and, when relevant, installation and service of automobile-related products. .

A quality management system is set up by a company to achieve high levels of customer satisfaction and continual improvement, focusing on defect prevention and the reduction of variation and waste in the supply chain. This is done by

- establishing a quality policy and quality objectives, and
- establishing the means to achieve those objectives.

Rather than specify requirements for your final product – *what* you produce – ISO/TS 16949 focuses further "upstream" on the processes – or *how* you produce. ISO/TS 16949 requires documented systems for controlling the processes you use to develop and produce your products and/or deliver your services. This standard is based on the idea that there are certain elements every quality management system must have in place in order to ensure that quality products are consistently provided to the customer on time.

ISO/TS 16949 was prepared by committees that include representatives

from countries around the world including the International Automobile Task Force and Japan Automobile Manufacturers Association Inc. with support from the ISO technical committee responsible for Quality Management and Quality Assurance.

WHAT IS THE "PROCESS APPROACH"?

ISO 9000 Quality Management Systems – Fundamentals and Vocabulary defines a **process** as a *"set of interrelated or interacting activities which transforms inputs into outputs."* (See figure on next page.)

In a company, the output of a process often becomes the input to another "downstream" process. For example, the output of the Sales process may be the generation of a production order by Sales or Production Control, which becomes one of the inputs to the Production process.

By identifying and managing all "processes" in your company (and the interactions and handoffs between these processes), your company is embracing the "Process Approach" to management.
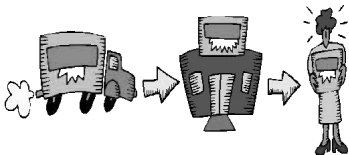
PROCESS

"A set of interrelated or interacting activities which transforms inputs into outputs."

INPUTS	TRANSFORMATION ACTIVITIES	OUTPUTS
• Materials • Environmental • People • Capital • Facilities • Information		• Goods • Information • Services • Etc.

EXAMPLE:

| INPUTS	ORDER REVIEW PROCESS	OUTPUTS
• Customer order • Customer requirements • Regulatory Requirements • Production Capacity • Etc.		• Production order
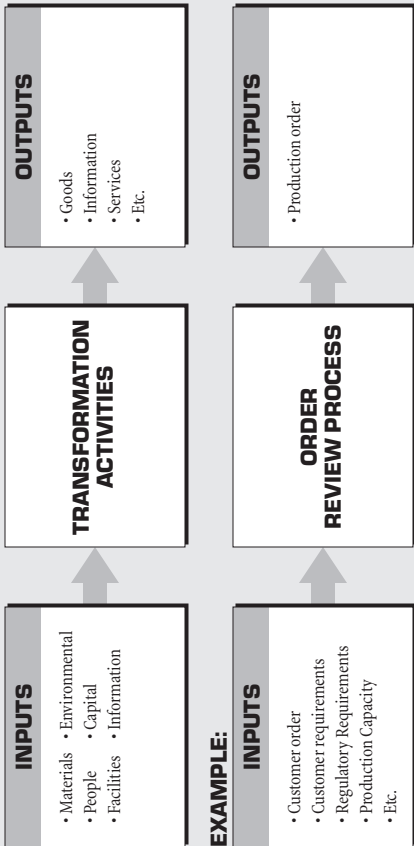
The ISO/TS 16949 standard is divided into five main sections that state requirements for the primary process "categories" in your company:

- *Quality Management System processes,* including developing the QMS documentation, documentation control and records control. These "QMS" requirements are found in Clause 4.
- *Management processes,* including planning and management review. These "Management Responsibility" requirements are found in Clause 5.
- *Resource management processes,* including human resources, infrastructure, and the work environment. These "Resource Management" requirements are found in Clause 6.
- *Product realization (production) processes,* including sales order review, product design, purchasing, calibration, and the actual "production" of your product or service. These "Product Realization" requirements are found in Clause 7.
- *Measurement, analysis and improvement processes,* including internal auditing, inspection, testing, and corrective/preventive action. These "Measurement, Analysis & Improvement" requirements are found in Clause 8.

EXAMPLE: FOUR TIER DOCUMENTATION STRUCTURE FOR CORRECTIVE ACTION

STANDARD   ISO/TS 16949 Clause 8.5.2

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LEVEL 1   Corrective Action Section
of QMS Manual

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LEVEL 2   Corrective Action Procedure

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LEVEL 3   Work Instruction on Using the
Corrective Action Request (CAR) form

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LEVEL 4   CAR (Record)
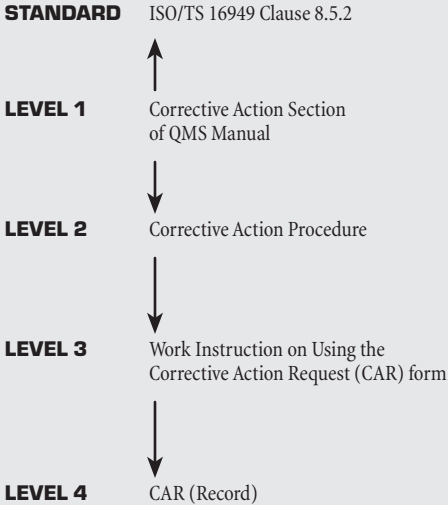
WHAT'S THE VALUE OF ALL THIS DOCUMENTATION?

There are many ways in which improved documentation can help a company to function better. A good documentation system should:

- Remove uncertainty and make your job easier.
- Allow for discovering new and better ways to perform your job.
- Ensure that key tasks can be carried out consistently even when the personnel who normally do them are absent.
- Increase quality awareness.
- Reduce the costs of poor quality.
- Improve communication within and between departments.
- Aid in the training of personnel.
- Provide correct, complete, and consistent ways to perform work and maintain high levels of quality.
- Provide assurance of adequate control in meeting customer needs.

HOW WILL THE DOCUMENTATION SYSTEM AFFECT ME AND MY JOB?

The implementation of ISO/TS 16949 will affect different jobs in different ways. You may be asked to do new things, such as helping to define and document the proper procedures and work instructions. If your company already has a complete documentation system in place, your job may not be affected much at all.

Some of the roles that almost every employee can expect to take on as part of the ISO/TS 16949 quality management system are to:

- Be familiar with the documentation that affects them.
- Consistently follow the quality management system documentation.
- Maintain complete and accurate records when necessary.
- Educate and guide others to use the ISO/TS 16949 quality management system correctly.

CLAUSE 5.2 CUSTOMER FOCUS

Essence of the clause: Top management must ensure that your organization and its quality management system are focused on meeting customer needs and creating value for its customers.

Who's most involved: Top management

This clause requires that your company have a strong understanding of your customers' needs and expectations, including quality levels, availability, servicing, etc., and that these requirements are communicated to the rest of the company. Statutory and regulatory requirements that relate to your products and processes (for example, requirements related to safety, emissions, hazardous materials, etc.) must also be determined and communicated throughout your company.

Customer Needs

Top management must also assign a "customer representative" who will ensure that the customers' needs are met.

5.5.3 Internal Communication

Your company must have processes for communicating important information about the quality management system and its effectiveness. Such information may include:

- Quality policy and quality objectives
- Internal and external audit results
- Customer satisfaction data
- Product and process measurement data

Mechanisms for internal communication may include periodic meetings, email, bulletin boards, and suggestion boxes.

MEASUREMENT, ANALYSIS & IMPROVEMENT

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CLAUSE 8.1 GENERAL

Essence of the clause: To make sure your company is producing a quality product and to continually improve, monitoring and measuring activities must be planned and performed.

Who's most involved: Management (of almost every department)

This clause requires your company to measure its products, processes, and customers' satisfaction to provide confidence that the quality management system is "working" and to prioritize improvement efforts.

Basic statistical concepts (such as variation and process capability) must be understood and used throughout the company, and statistical methods (such as Statistical Process Control) to gather, present, and analyze data must also be considered.

Specific monitoring and measurement requirements are detailed in clause 8.2.

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CLAUSE

8

MEASUREMENT, ANALYSIS & IMPROVEMENT

By effectively planning and committing to these processes, your company will depend less and less on reacting to problems ("fire-fighting"), and more on proactive improvements.

8.5.2 Corrective Action and 8.5.3 Preventive Action

These sub-clauses require your company to have documented procedures for both corrective and preventive action. These actions are intended to eliminate the causes of nonconformities by making corrections to the quality management system. In particular, corrective action deals with *actual* problems and preventive action deals with *potential* problems.

Notice the difference between these sub-clauses and clause 8.3 (Control of Nonconforming Product). Control of nonconforming product is about putting defective product right; corrective and preventive actions are about putting the quality management system right.

In general, corrective and preventive actions may be triggered by:
- Findings from internal or third-party audits.
- Management review results.
- Data analysis.
- Information on returned product and customer feedback.
- Other sources of information on nonconformities.

ISO/TS 16949 also requires your company to:
- Have a problem solving process for identifying and eliminating the root causes of problems;

- Use error-proofing methods in the corrective action process to help prevent recurrence of the problem;
- Apply the results of effective corrective actions to other similar processes and products; and
- Analyze parts rejected by your customers and take corrective action to prevent recurrence.

Checklist

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It's important to understand that internal audits are trying to find problems with the **quality management system,** not with the people who are carrying it out. They are not intended to place blame on anyone. If someone is not carrying out a procedure correctly, it should be viewed as a system problem (such as lack of proper training or motivation, incomplete or incorrect documentation, etc.).

WHAT ARE AUDITORS LOOKING FOR?

On each audit, auditors will only be looking at a **sample** of the quality management system. They obviously will not have time to look at everything in the company that affects quality, so the auditors will try to pick out what they feel are the more important activities.

They will also check up on areas that have had problems in the past to see how they are improving.

In general, auditors are looking for:

- Evidence that the system (as **documented**) meets customer requirements and the requirements stated in ISO/TS 16949.
- Evidence that all employees understand the documentation that affects them.
- Evidence that the system (as **implemented**) works according to planned arrangements (such as the instructions stated in your quality management system documentation or in agreements with customers).
- Evidence that the system is effective in providing quality products and services.

In order to find such evidence, auditors will be looking at a lot of documents and talking to people about how they use the documentation and carry out their work. The type of evidence an auditor finds might be in the form of something the auditor sees or hears. For example:

- out-of-date documentation;

HOW DO I ANSWER AN AUDITOR'S QUESTIONS?

The best guideline for answering an auditor's questions is sometimes a surprise to people… Simply be polite and honest. In general, the auditor is not out to trick or deceive you, so you should return the favor. There are a few other tips you should know when talking to auditors:

- When talking to an **internal auditor**, you should feel free to offer any information on the subject being addressed that you feel is important, even if it's not specifically asked for. Your internal auditors are there to help improve the system for everyone. Don't be afraid to ask the internal auditor a question or ask for advice.
- When talking to a **third-party auditor** (your registrar's auditor), you should still be honest, but **only answer their question**. There is no need to volunteer information with third-party auditors.
- **Never lie** to an auditor… They often know the right answer before they ask the question.
- Answer the auditor's question directly and with confidence when you know the answer.

If you don't feel very confident about answering a question, you can:
- Tell the auditor you don't understand the question, and ask him or her to restate it.
- Take the time to find the answer in your area's quality procedures or work instructions. (Remember, that's what they're there for!)
- Ask someone else, such as your manager, for help in answering the question (especially if you feel the question falls outside your job responsibilities).

Remember that the auditors want you to succeed. They are not "out to get you."