

D 16

ISO/TS 16 949 readiness

Goal

1 Quality approach

1.1 Background

1.2 Scope

2 Principles and steps

3 Process approach

3.1 Definitions

3.2 Process

3.2.1 Management process

3.2.2 Realization process

3.2.3 Support process

3.3 Process mapping

3.4 Process approach

4 Quality management system (QMS) requirements

4.1 General requirements

4.2 Documentation

5 Management responsibility

5.1 Commitments

5.2 Management review

6 Resource management

7 Product realization

7.1 Planning

7.2 Customer

7.3 Design and development

7.4 Purchasing

7.5 Production

7.6 Monitoring and measuring

8 Measurement, analysis and improvement

8.1 General

8.2 Internal audit

8.3 Nonconforming product

8.4 Analysis of data

8.5 Improvement

8.5.1 Continual improvement

8.5.2 Corrective action

8.5.3 Preventive action

Annexes

Goal of the module: Readiness for implementation, certification, maintenance and improvement of your quality management system for automotive production (ISO/TS 16 949) so as to be able to:

- increase the satisfaction of stakeholders
- improve economic and financial results
- demonstrate conformity to customer automotive, statutory and regulatory requirements

1 Quality approach

1.1 Background

The quality management systems (QMS) ISO 9000 standards have appeared in:

- 1987: ISO 9000 first edition: ISO 9001; ISO 9002; ISO 9003; ISO 9004
- 1994: ISO 9000 first revision: ISO 9001; ISO 9002; ISO 9003; ISO 9004 – more understandable, customer focus better defined, preventive actions added
- 2000: ISO 9000 second : ISO 9000; ISO 9001; ISO 9004 – simplified structure (8 clauses), priority to process approach and customer satisfaction
- 2008: third revision (fourth edition of ISO 9001): clarification of the requirements (no new requirement), better alignment with ISO 14 001

The ISO standards (more than 15 600) are used in countless fields and are recognized all over the world. ISO is the international organization for standardization and was created in 1947.

The ISO 9000 family of standards contains three core booklets:

- **ISO 9000 (2005): Quality management systems - Fundamentals and vocabulary**
- **ISO 9001 (2008): Quality management systems - Requirements**
- **ISO 9004 (2009): Managing for the sustained success of an organization - A quality management approach**

A specialised laboratory standard:

- **ISO 17 025 (2005): General requirements for the competence of testing and calibration laboratories**

All these standards and many more can be ordered on the [ISO](#) site.

The automotive standards have appeared in the 1990s (AVSQ = FIAT, VDA = BWM + VW + Daimler, Valéo...):

- 1994: EAQF (PSA + Renalt); QS 9000 (Chrysler + Ford + GM)
- 1998: QS 9000 third version
- 1999: ISO/TS 16 949 first version
- 2002: ISO/TS 16 949 second version
- 2009: ISO/TS 16 949 third version

The role of the IATF (International Automotive Task Force) was essential to replace the existing standards in different countries with a single technical specification:

ISO/TS 16 949: Quality management systems. Particular requirements for the application of ISO 9001: 2008 for automotive production and relevant service part organizations

This allows a single certification recognized worldwide for any organization linked to automotive production. The requirements of ISO/TS 16 949 and the specific requirements of customers are the basis of any quality management system for automotive manufacturers.

The technical specification ISO/TS 16 949 fully resumes the 8 clauses of ISO 9001: 2008 (boxed text) and adds the specific requirements for the automotive industry (81 subclauses, 49 notes and one normative annex). Some of these requirements:

- business plan
- special characteristics
- Advanced Product Quality Planning (APQP)
- analysis of potential risks (Failure Mode and Effects Analysis, FMEA)
- control plan
- laboratory control
- product acceptance process (Production Part Approval Process, PPAP)
- measurement systems analysis (MSA)
- statistical process control (SPC)

For more information on these core tools you can consult the following manuals:

- Production Part Approval Process (PPAP), 2006, [AIAG](#)
- Analysis techniques for system reliability. Procedure for failure mode and effects analysis (FMEA), 2006, [IEC](#)
- Potential Failure Mode and Effects Analysis (FMEA), 2008, [AIAG](#)
- Advanced Product Quality Planning (APQP), 2008, [AIAG](#)
- Measurement Systems Analysis (MSA) - 2010, [AIAG](#)
- Statistical Process Control (SPC) - 2005, [AIAG](#)
- Effective Problem Solving Guideline - Continuous Quality Improvement (CQI -10) - 2006, [AIAG](#)
- ISO/TS 16949:2009 Guidance Manual - Continuous Quality Improvement (CQI -16) - 2009, [AIAG](#)

The standards of the series **ISO 10 001** to **ISO 10 019** are guidelines for quality management systems and will help you find many answers (cf. ISO 9004:2009, Bibliography).

1.2 Scope

The ISO/TS 16 949 technical specification is applied to any organization (without limitations about size) manufacturing automotive products in the scope of design, development, production and relevant service.

Some requirements of clause 7.3 can be excluded when the responsibility of product design and development is outsourced. This is possible when these exclusions:

- do not affect in any case product conformity linked to:
 - customer requirements
 - applicable regulation requirements
- do not release the organization of its responsibilities
- are justified in the quality manual
- do not concern design manufacturing processes

2 Principles and steps

Quality is anything that can be improved. Masaaki Imai

Quality approach is a state of mind which starts with top management as a priority strategic decision and extends to all employees. Top management defines the quality policy which