TECHNICAL SPECIFICATION

ISO/TS 16949

First edition
1999-03-01

Quality systems — Automotive suppliers — Particular requirements for the application of ISO 9001:1994

Systèmes qualité — Fournisseurs de l'automobile — Exigences particulières pour l'application de l'ISO 9001:1994

Reference number
ISO/TS 16949:1999(E)

International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Internet iso@iso.ch

Printed in Switzerland

Automotive Industry Action Group (AIAG)
26200 Lahser Road, Suite 200 Southfield, Michigan 48034 USA
tel. +1 (248) 358-35 70 fax: +1 (248) 358-3253 e-mail: bbaker@aiag.org

Associazione Nazionale Fra Industrie Automobilistiche (ANFIA/Italy)

Comité des Constructeurs Français d'Automobiles (CCFA/France)

Fédération des Industries des Équipements pour Véhicules (FIEV/France)

Verband der Automobilindustrie (VDA/Germany)
Qualitätsmanagement Center (QMC)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by 50 % of the members of the parent committee casting a vote;

— an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed every three years with a view to deciding whether it can be transformed into an International Standard.

ISO/TS 16949 was prepared by the International Automotive Task Force (IATF) and representatives from ISO/TC 176, *Quality management and quality assurance*, and its subcommittees.

Boxed text in copyright notice, clause 4 and annex A is original ISO 9001:1994 text. The sector-specific supplemental requirements are outside the boxes.

In this Technical Specification, the word "shall" indicates requirements. Paragraphs marked "**NOTE**" are for guidance in understanding or clarifying the associated requirement. The word "should" appearing in a **NOTE** is for guidance only.

Where the term "such as" is used, any suggestions given are for guidance only.

ISO/TS 16949 has been issued for provisional application in the automotive sector so that information and experience in its use may be gathered.

Remarks for certification

To obtain recognition of certification to this Technical Specification by the customer members of the IATF, a common global certification scheme has been developed and must be followed (see bibliography [7]). Customer-specific requirements supplemental to this Technical Specification, if any, shall be included in the audit in order to obtain customer recognition of such certification.

Details can be obtained from the organizations who support the International Automotive Task Force cited below.

NOTE All participating IATF OEMs and suppliers have customer-specific requirements in addition to this Technical Specification.

Associazione Nazionale Fra Industrie Automobilistiche (ANFIA)
Corso Gallileo Ferraris, 61 I-10128 Torino Italy
tel. +39 011 554 65 11 fax: +39 011 54 59 86 e-mail: anfia@anfia.it

Automotive Industry Action Group (AIAG)
26200 Lahser Road, Suite 200 Southfield, Michigan 48034 USA
tel. +1 (248) 358-35 70 fax: +1 (248) 358-3253 e-mail: bbaker@aiag.org

Comité des Constructeurs Français d'Automobiles (CCFA)
2, rue de Presbourg F-75008 Paris France
tel. +33 1 49 52 51 73 fax: +33 1 49 52 52 25 e-mail: mbehaghe@ccfa.fr

Fédération des Industries des Équipements pour Véhicules (FIEV)
79, rue J.J. Rousseau F-92158 Suresnes Cedex France
tel. +33 1 46 25 02 30 fax: +33 1 46 97 00 80 e-mail: fiev@fiev.fr

Society of Motor Manufacturers and Traders Ltd. (SMMT Ltd.)
Forbes House, Halkin Street London SW1X 7DS UK
tel. +44 171 235 70 00 fax: +44 171 235 71 12 e-mail: quality@smmt.co.uk

Verband der Automobilindustrie (VDA) Qualitätsmanagement Center (QMC)
Westendstr. 61 D-60325 Frankfurt am Main Germany
tel. +49 69 9 75 07-332 fax: +49 69 9 75 07-331 e-mail: schulz@vda-qmc.de

Introduction

The goal of this Technical Specification is the development of fundamental quality systems that provide for continuous improvement, emphasizing defect prevention and the reduction of variation and waste in the supply chain. This Technical Specification defines the fundamental quality system requirements of the subscribing companies. It is recognized that there may be company-specific, division-specific, commodity-specific, and/or part-specific requirements in addition to those given in Figure 1.

This Technical Specification aligns existing automotive quality system requirements within the global automotive industry and avoids multiple certification audits.

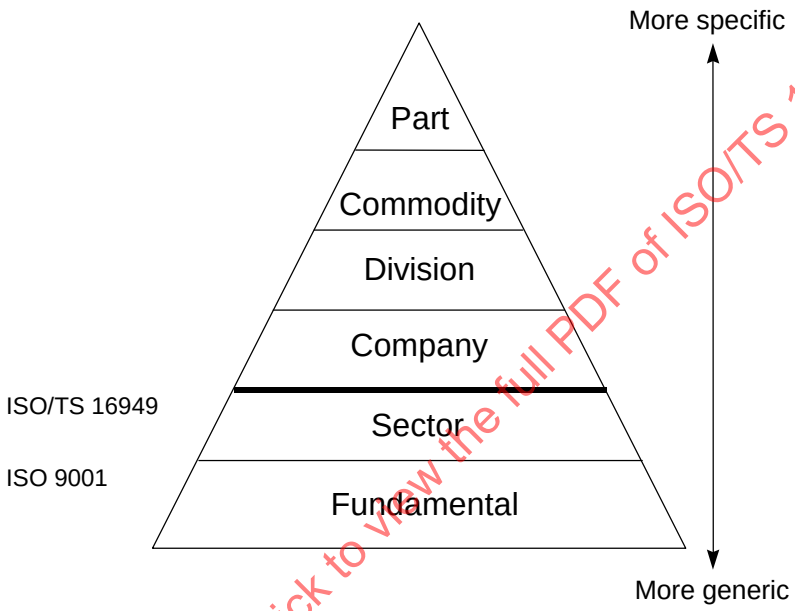
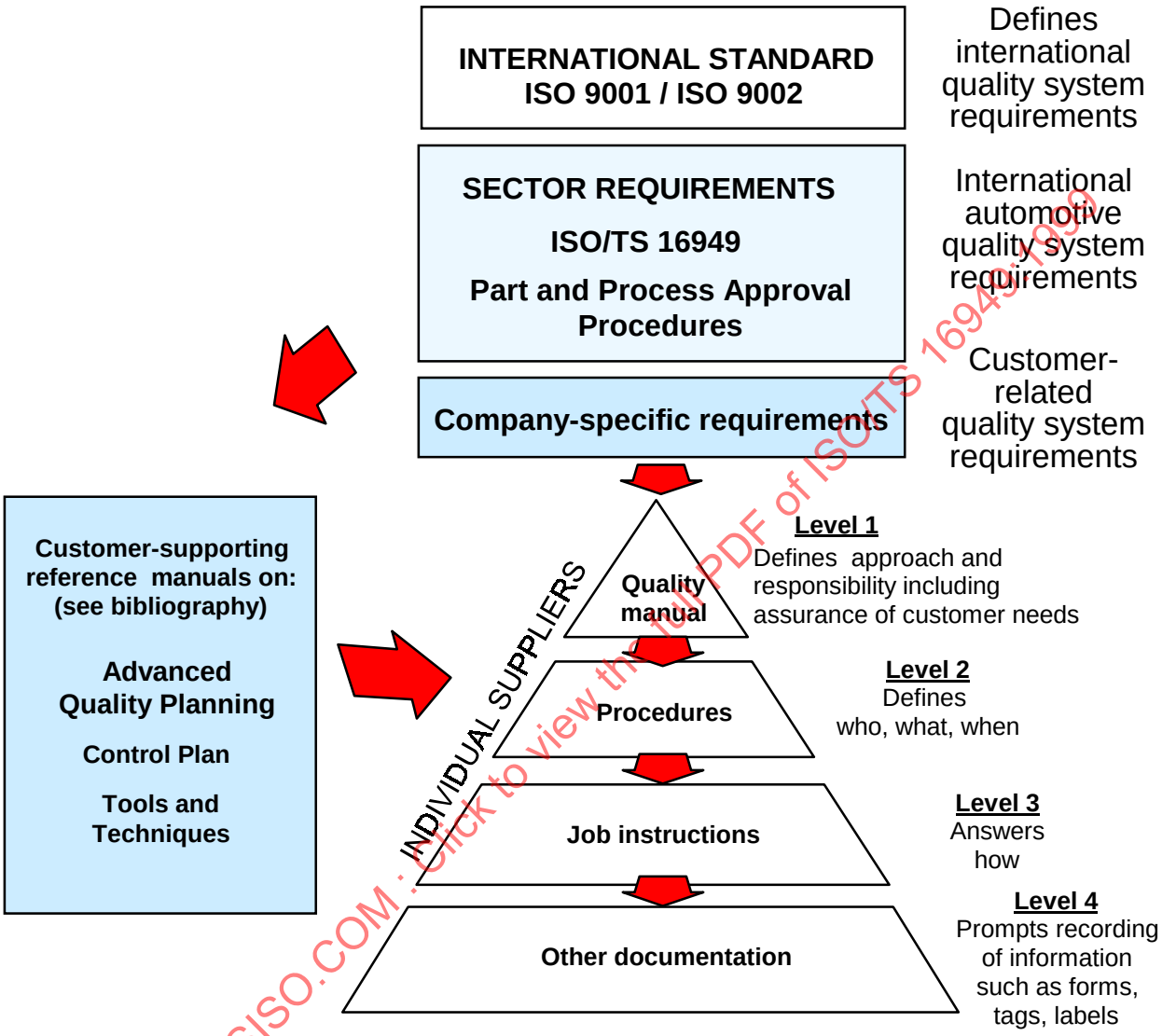


Figure 1 — Quality related requirements

Figure 2 demonstrates the progression of quality system documentation.



NOTE Once recorded, level 4 items may become a quality record (see 4.16).

Figure 2 — Quality System Documentation Progression

In this Technical Specification, quality planning activities of all pre-launch phases have been integrated under the new heading: "Product realization".

For suppliers with product design responsibility, product realization also includes product design (see 4.4).

Product realization in the context of quality planning is discussed in 4.2.4. The structure is outlined below:

- 4.2.3 Quality planning
  - 4.2.3.1 Quality planning – ISO 9001:1994
  - 4.2.3.2 Quality plan requirements
- 4.2.4 Product realization
  - 4.2.4.1 General
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Quality systems — Automotive suppliers — Particular requirements for the application of ISO 9001:1994

1 Scope

This Technical Specification specifies, in conjunction with ISO 9001:1994, the quality system requirements for the design/development, production and, when relevant, installation and servicing of automotive-related products.

This Technical Specification is applicable to production and service part supplier and subcontractor "sites" providing:

a) parts or materials, or

b) heat treating, painting, plating, or other finishing services, or

c) other customer-specified products.

NOTE "Remote locations" such as design centres and corporate headquarters form part of the site audit, however they cannot obtain stand-alone certification to this Technical Specification.

This Technical Specification can also be applied throughout the automotive supply chain.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this Technical Specification. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this Technical Specification are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 8402:1994, *Quality management and quality assurance — Vocabulary.*

ISO 9001:1994, *Quality systems — Model for quality assurance in design, development, production, installation and servicing.*

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*[1].

3 Terms and definitions

For the purposes of this Technical Specification the terms and definitions given in ISO 8402:1994 and in annex A apply. However where there are terms for which the wording of the definition differs in ISO 8402:1994, the definitions in annex A apply.

[1] Revision of ISO/IEC Guide 25:1990.

4 Quality system requirements

4.1 Management responsibility

4.1.1 Quality policy

4.1.1.1 Quality policy – ISO 9001:1994

The supplier's management with executive responsibility shall define and document its policy for quality, including objectives for quality and its commitment to quality. The quality policy shall be relevant to the supplier's organizational goals and the expectations and needs of its customers. The supplier shall ensure that this policy is understood, implemented and maintained at all levels of the organization.

4.1.1.2 Objectives

The supplier shall define goals, objectives and measurements to deploy the quality policy. Objectives for achieving quality shall be included in the business plan.

NOTE The goals and objectives should address customer expectations and be achievable within a defined time period.

4.1.1.3 Customer satisfaction

The supplier shall have a documented process for determining customer satisfaction, including frequency of determination, and how objectivity and validity are assured. Indicators to monitor trends of customer satisfaction and dissatisfaction shall be documented and supported by objective information.

NOTE Consideration should be given to both internal and external customers.

4.1.1.4 Continuous improvement

Continuous improvement in quality, service, cost, and technology shall be provided for in the Quality Policy.

The supplier shall identify opportunities for quality and productivity improvement and implement appropriate improvement projects.

The supplier shall use appropriate continuous improvement measures and methodologies (see 4.2.7).

NOTE 1 The following list shows examples of possible techniques which might be used. There may be many other methods which meet specific supplier needs more appropriately:

- control charts (variables, attributes, CUSUM),
- design of experiments (DOE),
- theory of constraints,
- overall equipment effectiveness,
- parts per million (PPM) analysis to achieve zero defects,
- value analysis,
- benchmarking,
- analysis of motion/ergonomics,
- mistake-proofing.

NOTE 2 Guidelines for quality improvement are given in ISO 9004-4.

4.1.2 Organization

4.1.2.1 Responsibility and authority

4.1.2.1.1 Responsibility and authority – ISO 9001:1994

The responsibility, authority and the interrelation of personnel who manage, perform and verify work affecting quality shall be defined and documented, particularly for personnel who need the organizational freedom and authority to:

a) initiate action to prevent the occurrence of any nonconformities relating to the product, process and quality system;

b) identify and record any problems relating to the product, process and quality system;

c) initiate, recommend or provide solutions through designated channels;

d) verify the implementation of solutions;

e) control further processing, delivery or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.

4.1.2.1.2 Customer representative

The supplier shall assign responsibility to appropriate individuals to represent the needs of the customer in internal functions in addressing quality requirements, such as selection of special characteristics, setting quality objectives, training, corrective and preventive actions, product design and development.

4.1.2.1.3 Quality responsibility

Management with responsibility and authority for corrective action shall be promptly informed of products or processes which become noncompliant with specified requirements.

Personnel responsible for quality shall have the authority to stop production to correct quality problems.

4.1.2.2 Resources

4.1.2.2.1 Resources – ISO 9001:1994

The supplier shall identify resource requirements and provide adequate resources, including the assignment of trained personnel (see 4.18), for management, performance of work and verification activities including internal quality audits.

NOTE Subclause 4.18 in ISO 9001:1994 is 4.18.1 in this Technical Specification.

4.1.2.2.2 Shift resources

Especially concerning the production process, all the shifts shall be staffed with personnel in charge of, or delegated responsibility for quality.

4.1.2.3 Management representative

The supplier's management with executive responsibility shall appoint a member of the supplier's own management who, irrespective of other responsibilities, shall have defined authority for

a) ensuring that a quality system is established, implemented and maintained in accordance with this International Standard, and

b) reporting on the performance of the quality system to the supplier's management for review and as a basis for improvement of the quality system.

NOTE The responsibility of a management representative may also include liaison with external parties on matters relating to the supplier's quality system.

4.1.2.4 Organizational interfaces

The supplier shall have systems in place to ensure management of appropriate activities during concept development, prototype and production according to customer advanced product quality planning and control plan manual or project management manual (see bibliography).

The supplier shall use a multidisciplinary approach for decision making and have the ability to communicate necessary information in a language used by the customer, unless waived by the customer, and data in the customer-prescribed format.

4.1.3 Management review

4.1.3.1 Management review – ISO 9001:1994

The supplier's management with executive responsibility shall review the quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of this International Standard and the supplier's stated quality policy and objectives (see 4.1.1). Records of such reviews shall be maintained (see 4.16).

NOTE Subclauses 4.1.1 and 4.16 in ISO 9001:1994 are 4.1.1.1 and 4.16.1 in this Technical Specification.

4.1.3.2 Management review – supplemental

These reviews shall include all elements of the quality system and its performance (see 4.2.8) over time as an essential part of the continuous improvement process.

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

NOTE Management review should be conducted with sufficient frequency to ensure that the established quality system is effective.

4.1.4 Business plan

The supplier shall utilize a formal, documented, comprehensive business plan. The business plan shall be a controlled document.

NOTE 1 The content of the business plan is not subject to third-party audit.

Goals and plans shall cover short-term (1 to 2 years) and longer-term (3 years or more). The goals and plans shall be based on analysis of competitive products, where available, and on benchmarking inside and outside the automotive industry and the supplier's commodity. Methods to determine current and future customer expectations shall be in place. An objective process shall be used to define the scope and collection and analysis of information, including the frequency and methods of collection.

Methods to track, update, revise and review the plan shall be documented to ensure that the plan is followed and communicated throughout the organization, as appropriate.

NOTE 2 This plan may typically include as applicable:

- market-related issues including customer satisfaction plans,
- financial planning and cost objectives,
- growth projections including plant/facilities plans,
- human resource development,
- R & D plans, projections, and projects with appropriate funding,
- operational performance objectives, measurables and improvement plan,
- health, safety and environmental issues.

4.1.5 Analysis and use of company level data

The supplier shall document trends in quality, operational performance (productivity, costs of poor quality, efficiency, effectiveness) and current quality levels for key product and service features.

NOTE These should be compared with those of competitors and/or appropriate benchmarks.

Trends in data and information shall be compared with progress toward overall business objectives and lead to action to support the following:

a) development of priorities for prompt solutions to customer-related problems;
b) determination of key customer related trends and correlation to support status review, decision making and longer term planning;
c) an information system for the timely reporting of product information arising from usage.

4.1.6 Employee motivation, empowerment and satisfaction

The supplier shall have a process for motivation of employees to achieve quality objectives and to make continuous improvements. The process shall include promotion of quality awareness on all levels.

NOTE Quality reviews should be conducted to provide appropriate information, such as "plan/actual" comparison and improvement suggestions.

The supplier shall have a process for measurement of employee satisfaction and employee understanding of appropriate quality objectives.

4.1.7 Impact on society

4.1.7.1 Product safety

Due care regarding product safety and means to minimize potential risks to employees, customers, users and the environment shall be addressed in the supplier's quality policy and practices, especially in design control (see 4.4) and process control (see 4.9) procedures and practices. The supplier shall promote internal awareness of safety considerations relative to the supplier's product.

4.1.7.2 Regulations

The supplier shall have a process to ensure compliance with all applicable government, safety and environmental regulations, including those concerning storage, handling, recycling, eliminating or disposing of materials.

4.2 Quality system

4.2.1 General

The supplier shall establish, document and maintain a quality system as a means of ensuring that product conforms to specified requirements. The supplier shall prepare a quality manual covering the requirements of this International Standard. The quality manual shall include or make reference to the quality system procedures and outline the structure of the documentation used in the quality system.

NOTE 1 Guidance on quality manuals is given in ISO 10013.

NOTE 2 All the quality system documents should be controlled. See Figure 2.

4.2.2 Quality system procedures

4.2.2.1 Quality system procedures – ISO 9001:1994

The supplier shall:

a) prepare documented procedures consistent with the requirements of this International Standard and the supplier's stated quality policy, and

b) effectively implement the quality system and its documented procedures.

For the purposes of this International Standard, the range and detail of the procedures that form part of the quality system shall be dependent upon the complexity of the work, the methods used, and the skills and training needed by personnel involved in carrying out the activity.

NOTE Documented procedures may make reference to work instructions that define how an activity is performed.

4.2.2.2 Quality system documentation

All requirements of this Technical Specification shall be addressed in the quality system documentation, but not necessarily by individual procedures.

4.2.3 Quality planning

4.2.3.1 Quality planning – ISO 9001:1994

The supplier shall define and document how the requirements for quality will be met. Quality planning shall be consistent with all other requirements of a supplier's quality system and shall be documented in a format to suit the supplier's method of operation. The supplier shall give consideration to the following activities, as appropriate, in meeting the specified requirements for products, projects or contracts:

a) the preparation of quality plans;

b) the identification and acquisition of any controls, processes, equipment (including inspection and test equipment), fixtures, resources and skills that may be needed to achieve the required quality;

c) ensuring the compatibility of the design, the production process, installation, servicing, inspection and test procedures and the applicable documentation;

d) the updating, as necessary, of quality control, inspection and testing techniques, including the development of new instrumentation;

e) the identification of any measurement requirement involving capability that exceeds the known state of the art, in sufficient time for the needed capability to be developed;

f) the identification of suitable verification at appropriate stages in the realization of product;

g) the clarification of standards of acceptability for all features and requirements, including those which contain a subjective element;

h) the identification and preparation of quality records (see 4.16).

NOTE 1 The quality plans referred to [see 4.2.3 a)] may be in the form of a reference to the appropriate documented procedures that form an integral part of the supplier's quality system.

NOTE 2 Subclauses 4.2.3 a) and 4.16 in ISO 9001:1994 are 4.2.3.1 a) and 4.16.1 respectively in this Technical Specification.

4.2.3.2 Quality plan requirements

The supplier shall have a quality plan which includes customers' requirements and references to appropriate technical specifications.

4.2.4 Product realization

4.2.4.1 General

The supplier shall have a process for product realization to deliver products on time to customer requirements (quality, cost, delivery). For suppliers with product design responsibility, this process shall include product design (see 4.4).

NOTE 1 Some customers refer to project management as a means for product realization, while others consider advanced quality planning as the means. Quality planning embodies the concepts of defect prevention and continuous improvement as contrasted with defect detection.

If a project management approach is used, a project manager and a project team shall be assigned, appropriate resources shall be allocated (see 4.1.2.2) and any special responsibilities (see 4.1.2.1) and organizational interfaces (see 4.1.2.4) shall be defined.

NOTE 2 The project should be broken down into elementary tasks.

The supplier shall ensure the confidentiality of customer-contracted products and projects under development and related product information.

4.2.4.2 Measurements

Measurements at appropriate stages of product realization shall be defined, analysed and reported to management. These measurements shall include quality risks, costs, lead-times, critical paths and others, as appropriate.

4.2.4.3 Review cycle

The supplier shall review the status at appropriate stages of product realization and take suitable action.

NOTE These reviews should be coordinated with the design phases (see 4.4) and should include process design (4.2.4.10).

4.2.4.4 Multidisciplinary approach

The supplier shall use a multidisciplinary approach to prepare for product realization, including:

- development/ finalization of special characteristics,
- development, and review of FMEAs (see A.27) including actions to reduce potential risks,
- development, and review of control plans.

4.2.4.5 Tools and techniques

The supplier shall use tools and techniques identified in customer reference manuals on advanced product quality planning and control plan. Similar techniques that accomplish the intent may be acceptable.

The supplier shall carry out analysis of potential nonconformities and shall implement appropriate action. Process FMEAs shall include all special characteristics. Customers may have FMEA and control plan review and approval requirements which shall be observed.

The supplier shall utilize appropriate mistake-proofing methods during the planning of processes, facilities, equipment and tooling.

The supplier shall perform process studies on all new processes to verify process capability and to provide additional input for process control. The results of process studies shall be documented with specifications where applicable for means of production, measurement and test, and maintenance instructions. These documents shall include objectives for process capability, reliability, maintainability and availability, as well as acceptance criteria.

4.2.4.6 Computer-aided design

When specified in the contract, the supplier shall have the appropriate resources and equipment to utilize computer-aided product design, engineering and analysis compatible with the customer systems, including subcontracted design work. The supplier shall also be able to use numerical design and drawing data, by computer-aided methods, for the manufacture of production tooling, and prototypes as applicable. If these functions are subcontracted, the supplier shall provide technical leadership.

4.2.4.7 Special characteristics

The supplier shall apply appropriate methods to identify special characteristics (see annex C).

NOTE 1 Special characteristics may include product characteristics and process parameters.

All special characteristics shall be included in the control plan.

Customers may have specific definitions and symbols which shall be complied with.

Process control documents such as FMEAs, control plans and operator instructions shall be marked with the customer's special characteristic symbol or the supplier's equivalent symbol or notation to indicate those process steps that affect special characteristics.

NOTE 2 Initially, the customer may determine special characteristics and identify them. Special characteristics may be identified from any product characteristic category, such as dimensional, material, appearance or performance.

4.2.4.8 Feasibility reviews

The supplier shall investigate and confirm the manufacturing feasibility of proposed products in contract review (see 4.3). Feasibility reviews shall be recorded.

4.2.4.9 Management of process design

4.2.4.9.1 General

The supplier shall establish and maintain documented procedures to develop and verify the design of processes used for product realization.

4.2.4.9.2 Process design input

The supplier shall identify, document and review the process design input requirements including:

- product design output data, such as design FMEAs,
- targets for productivity, process capability and cost,
- applicable regulations,
- customers requirements, if any,
- experience from previous developments.

4.2.4.9.3 Process design output

The process design output shall be expressed in terms that can be verified and validated against process design input requirements. The process design output shall include:

- specifications and drawings,
- process FMEAs,
- job instructions (see 4.9.2),
- process approval acceptance criteria,
- data for quality, reliability, maintainability and measurability,
- results of mistake-proofing activities, as appropriate,
- methods of rapid detection and feedback of product/process nonconformities.

4.2.4.9.4 Process verification

The supplier shall verify process design output against process design input requirements and record the results (see 4.16).

4.2.4.10 Control plan

The supplier shall:

- develop control plans (see annex B) at the system, subsystem, component and/or material level, as appropriate for the product supplied,
- have a control plan for pre-launch and production, and also for prototype when required by the customer,
- use a multidisciplinary approach to develop control plans,
- list on the control plan the controls used for process control (see 4.9),
- include the customer required information on the control plan (see annex B),
- initiate the specified reaction plan as appropriate (see 4.9.3).

NOTE 1 The control plan requirement encompasses processes producing bulk materials such as steel, plastic resin and paint as well as those producing parts.

Control plans shall be reviewed and updated as appropriate when any of the following occur:

- product is changed,
- processes are changed,
- processes become unstable,
- processes become non-capable,
- inspection method, frequency, etc. is revised.

NOTE 2 Customer approval may be required.

4.2.4.11 Product approval process

The supplier shall comply with a product and process approval procedure recognized by the customer.

NOTE 1 Part approval is the final step of the product realization process and will be completed after the process is verified.

This product approval process shall also be applied to subcontractors.

NOTE 2 Where no customer procedure exists, such as tier 3 companies, the supplier should comply with one of the part approval manuals listed in the bibliography.

The supplier shall verify that changes are validated including all subcontractor changes.

All changes shall require customer notification and may require customer approval. For proprietary designs, impact on form, fit, function, performance, and/or durability shall be reviewed with the customer so that all effects can be properly evaluated.

When required by the customer, additional verification/identification requirements such as those required for new model introduction shall be met.

4.2.5 Plant, facility and equipment planning

The supplier shall use a multidisciplinary approach for developing plant, facility and equipment plans. Plant layouts shall minimize material travel and handling, facilitate synchronous material flow, and optimize value-added use of floor space. Methods shall be developed for evaluating the effectiveness of existing operations considering the following factors:

- overall work plan,
- appropriate automation,
- ergonomics and human factors,

– operator and line balance,
– storage and buffer inventory levels,
– value-added labour content.

NOTE The supplier should identify and define appropriate metrics to monitor the effectiveness of existing operations.

4.2.6 Tooling management

The supplier shall provide appropriate technical resources for tool and gauge design, fabrication and verification activities.

The supplier shall establish and implement a system for tooling management including:

– maintenance and repair facilities and personnel,
– storage and recovery,
– set-up,
– tool-change programmes for perishable tools,
– tool design modification documentation, including engineering change level,
– tool modification and revision to documentation as appropriate,
– tooling identification defining the status, such as production, repair or disposal.

The supplier shall implement a system to track and follow-up on these activities if any work is subcontracted.

4.2.7 Process improvement

Continuous improvement shall extend to product characteristics and process parameters with the highest priority on special characteristics (see 4.1.1.4 and 4.2.4.7). The supplier shall develop a prioritized action plan.

NOTE 1 Efforts should be made to achieve defect prevention rather than defect detection.

NOTE 2 If attribute data (see 4.10.1.2) results do not equal zero defects, it is nonconforming product. "Improvements" made in these situations are corrective actions. Processes with unacceptable capability/performance require corrective action (see 4.14.2 and 4.13).

4.2.8 Quality system performance

The supplier shall evaluate the performance of the quality system to verify the effectiveness of its operation. Results shall be recorded to provide, as a minimum, evidence of the achievement of:

a) objectives specified in the quality policy (see 4.1.1.2),
b) objectives specified in the business plan (see 4.1.4),
c) customer satisfaction with product supplied.

The results shall be used for continuous improvement or corrective action as appropriate.

4.3 Contract review

4.3.1 General

The supplier shall establish and maintain documented procedures for contract review and for the coordination of these activities.

4.3.2 Review

4.3.2.1 Review – ISO 9001:1994

Before submission of a tender, or the acceptance of a contract or order (statement of requirement), the tender, contract, or order shall be reviewed by the supplier to ensure that:

a) the requirements are adequately defined and documented; where no written statement of requirement is available for an order received by verbal means, the supplier shall ensure that the order requirements are agreed before their acceptance;

b) any differences between the contract or order requirements and those in the tender are resolved;

c) the supplier has the capability to meet the contract or order requirements.

4.3.2.2 Review – supplemental

The supplier shall have a process for identification of cost elements or price, as appropriate, in developing quotations.

NOTE Cost data are not subject to third-party audit. Cost data refer to values while cost elements refer to items such as labour, overheads, material.

The supplier shall ensure that any customer-specific requirements are met [see also special characteristics (4.2.4.7) and feasibility review (4.2.4.8)].

4.3.3 Amendment to a contract

The supplier shall identify how an amendment to a contract is made and correctly transferred to the functions concerned within the supplier's organization.

4.3.4 Records

Records of contract reviews shall be maintained (see 4.16).

NOTE 1 Channels for communication and interfaces with the customer's organization in these contract matters should be established.

NOTE 2 Subclause 4.16 in ISO 9001:1994 is 4.16.1 in this Technical Specification.

4.4 Design control

IMPORTANT: THIS ELEMENT APPLIES TO PRODUCT DESIGN RESPONSIBLE SUPPLIERS ONLY. Customer approval of a product from a design responsible supplier does not waive the supplier's design responsible status.

4.4.1 General

The supplier shall establish and maintain documented procedures to control and verify the design of the product in order to ensure that the specified requirements are met.

4.4.2 Design and development planning

4.4.2.1 Design and development planning – ISO 9001:1994

The supplier shall prepare plans for each design and development activity. The plans shall describe or reference these activities, and define responsibility for their implementation. The design and development activities shall be assigned to qualified personnel equipped with adequate resources. The plans shall be updated, as the design evolves.

4.4.2.2 Required skills

The supplier shall ensure that the design team is qualified to achieve design requirements.

The supplier's design activity shall be qualified in appropriate skills such as:

- geometric dimensioning and tolerancing (GD&T),
- quality function deployment (QFD),
- design for manufacturing (DFM)/design for assembly (DFA),
- value engineering (VE),
- design of experiments (DOE),
- failure mode and effects analysis (DFMEA/PFMEA, etc.),
- finite element analysis (FEA),
- solid modelling,
- simulation techniques,
- computer-aided design (CAD)/computer-aided engineering (CAE),
- reliability engineering plans.

4.4.2.3 Research and development

The supplier shall have access to research and development facilities to ensure innovation of product and processes.

4.4.3 Organizational and technical interfaces

Organizational and technical interfaces between different groups which input into the design process shall be defined and the necessary information documented, transmitted and regularly reviewed.

4.4.4 Design input

4.4.4.1 Design input – ISO 9001:1994

Design input requirements relating to the product, including applicable statutory and regulatory requirements, shall be identified, documented and their selection reviewed by the supplier for adequacy. Incomplete, ambiguous or conflicting requirements shall be resolved with those responsible for imposing these requirements.

Design input shall take into consideration the results of any contract review activities.

4.4.4.2 Reliability objectives

Product life, reliability, durability and maintainability objectives shall be included in design inputs.

4.4.4.3 Use of information

The supplier shall have a process to deploy information gained from previous design projects, competitor analysis or other sources as appropriate, for current and future projects of a similar nature.

4.4.5 Design output

4.4.5.1 Design output – ISO 9001:1994

Design output shall be documented and expressed in terms that can be verified and validated against design input requirements.

Design output shall:

a) meet the design input requirements;

b) contain or make reference to acceptance criteria;

c) identify those characteristics of the design that are crucial to the safe and proper functioning of the product such as operating, storage, handling, maintenance, and disposal requirements.

Design output documents shall be reviewed before release.

NOTE The characteristics specified in c) above are designated as "special characteristics".

4.4.5.2 Design optimization

The supplier's design output shall be the result of a process that includes:

- efforts to simplify, optimize, innovate and reduce waste, such as quality function deployment (QFD), design for manufacturing (DFM), design for assembly (DFA), value engineering (VE), design of experiments (DOE), tolerance studies, or appropriate alternatives,
- utilization of geometric dimensioning and tolerancing as applicable,
- analysis of cost/performance/risk trade-offs,
- use of feedback from testing, production and from the field,
- use of design FMEAs.

4.4.6 Design review

At appropriate stages of design, formal documented reviews of the design results shall be planned and conducted. Participants at each design review shall include representatives of all functions concerned with the design stage being reviewed, as well as other specialist personnel, as required. Records of such reviews shall be maintained (see 4.16).

NOTE Subclause 4.16 in ISO 9001:1994 is 4.16.1 in this Technical Specification.

4.4.7 Design verification

At appropriate stages of design, design verification shall be performed to ensure that the design stage output meets the design stage input requirements. The design verification measures shall be recorded (see 4.16).

NOTE 1 In addition to conducting design reviews (see 4.4.6), design verification may include activities such as

- performing alternative calculations,
- comparing the new design with a similar proven design, if available,
- undertaking tests and demonstrations, and
- reviewing the design-stage documents before release.

NOTE 2 Subclause 4.16 in ISO 9001:1994 is 4.16.1 in this Technical Specification.

4.4.8 Design validation

4.4.8.1 Design validation – ISO 9001:1994

Design validation shall be performed to ensure that product conforms to defined user needs and/or requirements.

NOTE 1 Design validation follows successful design verification (see 4.4.7).

NOTE 2 Validation is normally performed under defined operating conditions.

NOTE 3 Validation is normally performed on the final product, but may be necessary in earlier stages prior to product completion.

NOTE 4 Multiple validations may be performed if there are different intended uses.

4.4.8.2 Design validation – supplemental

Design validation shall be performed in conjunction with customer programme timing requirements. Validation results shall be recorded (see 4.16). Design failures shall be documented in the validation records. Procedures for corrective and preventive action shall be followed in addressing such design failures.

4.4.8.3 Prototype programme

When required by the customer, the supplier shall have a prototype programme. The supplier shall use, wherever possible, the same subcontractors, tooling and processes as will be used in production.

All performance testing activities shall be monitored for timely completion and conformance to requirements.

While services may be subcontracted, the supplier shall provide technical leadership.

4.4.9 Design changes

4.4.9.1 Design changes – ISO 9001:1994

All design changes and modifications shall be identified, documented, reviewed and approved by authorized personnel before their implementation.

NOTE This includes changes to proprietary designs.

4.4.9.2 Evaluation of design change

The supplier shall address the impact of a design change on the systems in which the product is used, the customer assembly process, and other related products and systems.

4.5 Document and data control

4.5.1 General

The supplier shall establish and maintain documented procedures to control all documents and data that relate to the requirements of this International Standard including, to the extent applicable, documents of external origin such as standards and customer drawings.

NOTE Documents and data can be in the form of any type of media, such as hard copy or electronic media.

4.5.2 Document and data approval and issue

4.5.2.1 Document and data approval and issue – ISO 9001:1994

The documents and data shall be reviewed and approved for adequacy by authorized personnel prior to issue. A master list or equivalent document control procedure identifying the current revision status of documents shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

This control shall ensure that:

a) the pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed;

b) invalid and/or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;

c) any obsolete documents retained for legal and/or knowledge-preservation purposes are suitably identified.

NOTE Examples of appropriate documents referred to in a) are:

- engineering drawings,
- engineering standards,
- mathematical (CAD) data,
- inspection instructions,
- test procedures,
- work instructions,
- operations sheets,
- quality manual,
- operational procedures,
- quality assurance procedures,
- material specifications.

4.5.2.2 Engineering specifications

The supplier shall establish a procedure to assure the timely review, distribution and implementation of all customer engineering standards/specifications and changes. The supplier shall maintain a record of the date on which each change is implemented in production (see 4.16). Implementation shall include updates to all appropriate documents.

NOTE 1 An appropriate unit of measure for "timely review" would be business "days", not weeks or months.

NOTE 2 A change in these standards/specifications will require an updated record of customer production part approval when these specifications are referenced on the design record or if they affect documents of production part approval process, such as control plan, FMEAs, etc.

4.5.3 Document and data changes

Changes to documents and data shall be reviewed and approved by the same functions/organizations that performed the original review and approval, unless specifically designated otherwise. The designated functions/organizations shall have access to pertinent background information upon which to base their review and approval.

Where practicable, the nature of the change shall be identified in the document or the appropriate attachments.

4.6 Purchasing

4.6.1 General

4.6.1.1 General – ISO 9001:1994

The supplier shall establish and maintain documented procedures to ensure that purchased product (see 3.1) conforms to specified requirements.

NOTE Definition 3.1 in ISO 9001:1994 is A.45 in this Technical Specification.

4.6.1.2 Customer-approved subcontractors

Where specified by the contract (e.g. customer engineering drawing, specification), the supplier shall purchase products, materials or services from approved subcontractors. Other subcontractors may only be used after they have been approved by the customer.

The use of customer-designated subcontractors does not relieve the supplier of the responsibility for ensuring the quality of subcontracted parts, materials and services.

4.6.1.3 Regulatory compliance

All purchased products or materials used in part manufacture shall satisfy current regulatory requirements applicable to the country of manufacture and sale such as environmental, electrical, electromagnetic, and safety.

4.6.2 Evaluation of subcontractors

4.6.2.1 Evaluation of subcontractors – ISO 9001:1994

The supplier shall:

a) evaluate and select subcontractors on the basis of their ability to meet subcontract requirements including the quality system and any specific quality assurance requirements;

b) define the type and extent of control exercised by the supplier over subcontractors. This shall be dependent upon the type of product, the impact of subcontracted product on the quality of final product and, where applicable, on the quality audit reports and/or quality records of the previously demonstrated capability and performance of subcontractors;

c) establish and maintain quality records of acceptable subcontractors (see 4.16).

NOTE Subclause 4.16 in ISO 9001:1994 is 4.16.1 in this Technical Specification.

4.6.2.2 Subcontractor development

The supplier shall perform subcontractor quality system development with the goal of subcontractor compliance to this Technical Specification or an existing customer quality system requirements manual (see bibliography).

NOTE 1 Subcontractor assessment should occur at supplier-specified frequency. If part of subcontractor development, it should be conducted according to this Technical Specification by a customer-recognized second or third party. Acceptance of such assessments is not intended to limit more specific supplier/subcontractor quality system development.

NOTE 2 The prioritization of subcontractors for development is dependent upon for example the subcontractor's quality performance and the importance of the product, material or service supplied.

4.6.2.3 Scheduling subcontractors

The supplier shall require 100 % on-time delivery performance from subcontractors. The supplier shall provide appropriate planning information and purchase commitments to enable subcontractors to meet this expectation.

The supplier shall implement a system to monitor the delivery performance of subcontractors with corrective actions taken as appropriate. The supplier shall track incidents of premium freight regardless of whether the supplier or the subcontractor pays the premium.

4.6.3 Purchasing data

Purchasing documents shall contain data clearly describing the product ordered, including where applicable:

a) the type, class, grade or other precise identification;

b) the title or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data, including requirements for approval or qualification of product, procedures, process equipment and personnel;

c) the title, number and issue of the quality system standard to be applied.

The supplier shall review and approve purchasing documents for adequacy of the specified requirements prior to release.

4.6.4 Verification of purchased product

4.6.4.1 Supplier verification at subcontractor's premises

Where the supplier proposes to verify purchased product at the subcontractor's premises, the supplier shall specify verification arrangements and the method of product release in the purchasing documents.

4.6.4.2 Customer verification of subcontracted product

Where specified in the contract, the supplier's customer or the customer's representative shall be afforded the right to verify at the subcontractor's premises and the supplier's premises that subcontracted product conforms to specified requirements. Such verification shall not be used by the supplier as evidence of effective control of quality by the subcontractor.

Verification by the customer shall not absolve the supplier of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer.

4.7 Control of customer-supplied product

4.7.1 Control of customer-supplied product – ISO 9001:1994

The supplier shall establish and maintain documented procedures for the control of verification, storage and maintenance of customer-supplied product provided for incorporation into the supplies or for related activities. Any such product that is lost, damaged or is otherwise unsuitable for use shall be recorded and reported to the customer (see 4.16).

Verification by the supplier does not absolve the customer of the responsibility to provide acceptable product.

NOTE 1 Customer-owned returnable packaging is included in this element (see 4.15.4).

NOTE 2 Subclause 4.16 in ISO 9001:1994 is 4.16.1 in this Technical Specification.

4.7.2 Customer owned tooling

Customer-owned tools and equipment shall be permanently marked so that the ownership of each item is visually apparent.

4.8 Product identification and traceability

Where appropriate, the supplier shall establish and maintain documented procedures for identifying the product by suitable means from receipt and during all stages of production, delivery and installation.

Where and to the extent that traceability is a specified requirement, the supplier shall establish and maintain documented procedures for unique identification of individual product or batches. This identification shall be recorded (see 4.16).

IMPORTANT: The words "Where appropriate", above, do not apply.

NOTE Subclause 4.16 in ISO 9001:1994 is 4.16.1 in this Technical Specification.

4.9 Process control

4.9.1 General

4.9.1.1 General – ISO 9001:1994

The supplier shall identify and plan the production, installation and servicing processes which directly affect quality, and shall ensure that these processes are carried out under controlled conditions.

Controlled conditions shall include the following:

a) documented procedures defining the manner of production, installation and servicing, where the absence of such procedures could adversely affect quality;

b) use of suitable production, installation and servicing equipment, and a suitable working environment;

c) compliance with reference standards/codes, quality plans and/or documented procedures;

d) monitoring and control of suitable process parameters and product characteristics;

e) the approval of processes and equipment, as appropriate.

f) criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g. written standards, representative samples or illustrations);

g) suitable maintenance of equipment to ensure continuing process capability.

Where the results of processes cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use, the processes shall be carried out by qualified operators and/or shall require continuous monitoring and control of process parameters to ensure that the specified requirements are met.

The requirements for any qualification of process operations, including associated equipment and personnel (see 4.18), shall be specified.

NOTE 1 Such processes requiring pre-qualification of their process capability are frequently referred to as special processes.

Records shall be maintained for qualified processes, equipment and personnel, as appropriate (see 4.16).

NOTE 2 Subclauses 4.16 and 4.18 in ISO 9001:1994 are 4.16.1 and 4.18.1 in this Technical Specification.

4.9.1.2 Cleanliness of premises

The supplier shall maintain premises in a state of order, cleanliness and repair appropriate to the product manufactured [see 4.9.1.1 b)].

4.9.1.3 Contingency plans

The supplier shall prepare contingency plans, such as utility interruptions, labour shortages, key equipment failure, to reasonably protect the customer's supply of product in the event of emergency, excluding natural disaster and force majeur [see 4.9.1.1 b)].

4.9.1.4 Designation of special characteristics

The supplier shall comply with all customer requirements for designation, documentation and control of special characteristics. The supplier shall provide documentation showing compliance with these customer requirements as requested [see 4.9.1.1 d)].

4.9.1.5 Preventive maintenance

The supplier shall identify key process equipment and provide appropriate resources for machine/equipment maintenance and develop an effective planned total preventive maintenance system [see 4.9.1.1 g)]. As a minimum, this system shall include the following:

- planned maintenance activities,
- packaging and preservation of equipment, tooling and gauging,
- availability of replacement parts for key manufacturing equipment,
- documenting, evaluating and improving maintenance objectives,
- predictive maintenance methods.

NOTE Predictive maintenance methods should include a review of appropriate items such as the manufacturer's recommendations, storage, tool wear, optimization of uptime, correlation of SPC data to preventive maintenance activities, important characteristics of perishable tooling, fluid analysis, infrared monitoring of circuits and vibration analysis as appropriate.

4.9.2 Job instructions

The supplier shall prepare documented job instructions for all employees having responsibilities for the operation of processes. These instructions shall be accessible for use at the work station without disruption to the job.

These instructions shall be derived from appropriate sources such as the quality plan (see 4.2.3), the control plan (see 4.2.4.10) and the product realization process (see 4.2.4).

NOTE 1 Job instructions may take the form of process sheets, inspection and laboratory test instructions, shop travellers, test procedures, standard operation sheets, or other documents normally used by the supplier to provide the necessary information.

Job instructions shall include or reference, as appropriate:

- operation name and number keyed to the process flow diagram,
- part name and part number, or part family,
- current engineering level/date,
- required tools, gauges and other equipment,
- material identification and disposition instructions,
- customer and supplier designated special characteristics if any,
- relevant engineering and manufacturing standards,
- inspection and test instructions with acceptance criteria (see 4.10.4),
- reaction plans,
- revision date and approvals,
- visual aids,
- tool-change intervals and set-up instructions,
- SPC and other process-monitoring requirements.

NOTE 2 "Job instructions" are equivalent to "work instructions" referred to in ISO 9001:1994.

4.9.3 Maintaining process control

The supplier shall maintain or exceed process capability or performance as approved via customer part approval process. To accomplish this, the supplier shall ensure that the control plan and process flow diagram are implemented, including adherence to the specified

- measurement technique,
- sampling plans,
- acceptance criteria (see 4.10.1.2),
- reaction plans when the acceptance criteria are not met.

See customer-specific requirements on advanced quality planning.

Significant process events such as tool-change, machine repair, etc., shall be noted on the control charts (see 4.16).

NOTE When statistical data indicate a high degree of process capability, the supplier may revise the control plan, as appropriate (see bibliography for customer part approval manuals).

The supplier shall initiate the appropriate reaction plan from the control plan for characteristics that are either unstable or non-capable. These reaction plans shall include containment of process output and 100 % inspection, as appropriate. A corrective action plan shall then be completed by the supplier, indicating specific timing and assigned responsibilities to assure that the process becomes stable and capable. The plans are to be reviewed with, and approved by the customer when so required.

The supplier shall maintain records of effective dates of process changes.

4.9.4 Verification of job set-ups

Job set-ups shall be verified whenever a set-up is performed, such as an initial run of a job, material changeover, job change, significant time periods lapsed between runs, etc.

Job instructions shall be available for set-up personnel. The supplier shall use statistical methods of verification where applicable.

NOTE Last-off-part comparisons are recommended.

4.9.5 Appearance items

For suppliers manufacturing parts designated by the customer as "appearance items", the supplier shall provide:

- appropriate lighting for evaluation areas,
- masters for colour, grain, gloss, metallic brilliance, texture, distinctness of image (DOI) as appropriate,
- maintenance and control of appearance masters and evaluation equipment,
- verification that personnel making appearance evaluations are qualified to do so.

4.10 Inspection and testing

4.10.1 General

4.10.1.1 General – ISO 9001:1994

The supplier shall establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for the product are met. The required inspection and testing, and the records to be established, shall be detailed in the quality plan or documented procedures.

NOTE References to "quality plan" (4.10.2 to 4.10.4) should be interpreted as "control plan".

4.10.1.2 Acceptance criteria

Acceptance criteria for attribute data sampling plans shall be zero defects. Appropriate acceptance criteria for all other situations such as visual standards shall be documented by the supplier.

NOTE Some acceptance criteria require customer approval.

4.10.2 Receiving inspection and testing

4.10.2.1 The supplier shall ensure that incoming product is not used or processed (except in the circumstances described in 4.10.2.3) until it has been inspected or otherwise verified as conforming to specified requirements. Verification of conformance to the specified requirements shall be in accordance with the quality plan and/or documented procedures.

4.10.2.2 In determining the amount and nature of receiving inspection, consideration shall be given to the amount of control exercised at the subcontractor's premises and the recorded evidence of conformance provided.

4.10.2.3 Where incoming product is released for urgent production purposes prior to verification, it shall be positively identified and recorded (see 4.16) in order to permit immediate recall and replacement in the event of nonconformity to specified requirements.

NOTE Subclause 4.16 in ISO 9001:1994 is 4.16.1 in this Technical Specification.

4.10.2.4 Incoming product quality

The supplier's incoming quality system shall use one or more of the following methods, unless waived by the customer:

- receipt of, and evaluation of, statistical data by the supplier,
- receiving inspection and/or testing such as sampling based on performance,
- second or third party assessments or audits of subcontractor sites, when coupled with records of acceptable quality performance,
- part evaluation by an accredited laboratory.

4.10.3 In-process inspection and testing

The supplier shall:

a) inspect and test the product as required by the quality plan and/or documented procedures;

b) hold product until the required inspection and tests have been completed or necessary reports have been received and verified, except when product is released under positive-recall procedures (see 4.10.2.3). Release under positive-recall procedures shall not preclude the activities outlined in 4.10.3 a).

4.10.4 Final inspection and testing

4.10.4.1 Final inspection and testing – ISO 9001:1994

The supplier shall carry out all final inspection and testing in accordance with the quality plan and/or documented procedures to complete the evidence of conformance of the finished product to the specified requirements.

The quality plan and/or documented procedures for final inspection and testing shall require that all specified inspection and tests, including those specified either on receipt of product or in-process, have been carried out and that the results meet specified requirements.

No product shall be dispatched until all the activities specified in the quality plan and/or documented procedures have been satisfactorily completed and the associated data and documentation are available and authorized.

4.10.4.2 Layout inspection and functional testing

A layout inspection and a functional verification to applicable customer engineering material and performance standards shall be performed for all products at a sufficient frequency as specified in the control plan. Results shall be available for customer review.

4.10.5 Inspection and test records

The supplier shall establish and maintain records which provide evidence that the product has been inspected and/or tested. These records shall show clearly whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria. Where the product fails to pass any inspection and/or test, the procedures for control of nonconforming product shall apply (see 4.13).

Records shall identify the inspection authority responsible for the release of product (see 4.16).

NOTE Subclauses 4.13 and 4.16 in ISO 9001:1994 are 4.13.1 and 4.16.1 in this Technical Specification.

4.10.6 Laboratory requirements

Where inspection, testing and calibration services are conducted by a supplier's laboratory facility the laboratory shall comply with ISO/IEC 17025, including use of a laboratory scope.

NOTE Accreditation of supplier facilities to ISO/IEC 17025 or national equivalent is not required by, nor does it satisfy, all quality system requirements specified in this Technical Specification for a laboratory. Therefore, the laboratory should be included in the on-site audits.

Commercial/independent laboratory facilities used for inspection, test or calibration services by the supplier shall be accredited to ISO/IEC 17025 or national equivalent.

4.11 Control of inspection, measuring and test equipment

4.11.1 General

4.11.1.1 General – ISO 9001:1994

The supplier shall establish and maintain documented procedures to control, calibrate and maintain inspection, measuring and test equipment (including test software) used by the supplier to demonstrate the conformance of product to the specified requirements. Inspection, measuring and test equipment shall be used in a manner which ensures that the measurement uncertainty is known and is consistent with the required measurement capability.

Where test software or comparative references such as test hardware are used as suitable forms of inspection, they shall be checked to prove that they are capable of verifying the acceptability of product, prior to release for use during production, installation or servicing, and shall be rechecked at prescribed intervals. The supplier shall establish the extent and frequency of such checks and shall maintain records as evidence of control (see 4.16).

Where the availability of technical data pertaining to the inspection, measuring and test equipment is a specified requirement, such data shall be made available, when required by the customer or customer's representative, for verification that the inspection, measuring and test equipment is functionally adequate.

NOTE 1 For the purposes of this International Standard, the term "measuring equipment" includes measurement devices.

NOTE 2 Subclause 4.16 in ISO 9001:1994 is 4.16.1 in this Technical Specification.

4.11.1.2 Measurement system analysis

Appropriate statistical studies shall be conducted to analyse the variation present in the results of each type of measuring and test equipment system. This requirement shall apply to measurement systems referenced in the control plan (see 4.2.4.10). The analytical methods and acceptance criteria used shall conform to those in the customer reference manuals on measurement system analysis (see bibliography) as appropriate, including bias, linearity, stability and measurement repeatability and reproducibility studies. Other analytical methods and acceptance criteria may be used if approved by the customer.

NOTE The choice of the specific method to be used should be based upon sound technical knowledge of the complete measurement system, the conditions under which it will operate, and the uses for which the data are being produced.

4.11.2 Control procedure

The supplier shall:

a) determine the measurements to be made and the accuracy required, and select the appropriate inspection, measuring and test equipment that is capable of the necessary accuracy and precision;

b) identify all inspection, measuring and test equipment that can affect product quality, and calibrate and adjust them at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to internationally or nationally recognized standards. Where no such standards exist, the basis used for calibration shall be documented;

c) define the process employed for the calibration of inspection, measuring and test equipment, including details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria and the action to be taken when results are unsatisfactory;

d) identify inspection, measuring and test equipment with a suitable indicator or approved identification record to show the calibration status;

e) maintain calibration records for inspection, measuring and test equipment (see 4.16);

f) assess and document the validity of previous inspection and test results when inspection, measuring or test equipment is found to be out of calibration;

g) ensure that the environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out;

h) ensure that the handling, preservation and storage of inspection, measuring and test equipment is such that the accuracy and fitness for use are maintained;

i) safeguard inspection, measuring and test facilities, including both test hardware and test software, from adjustments which would invalidate the calibration setting.

NOTE 1 The metrological confirmation system for measuring equipment given in ISO 10012 may be used for guidance.

NOTE 2 Wear and frequency of use should be taken into account [see 4.11.2 c)].

NOTE 3 A serial number traceable to the device calibration record meets the intent of this requirement [see 4.11.2 d)].

NOTE 4 Subclause 4.16 in ISO 9001:1994 is 4.16.1 in this Technical Specification.

4.11.3 Records

Records (see 4.16) of the calibration activity for all gauges, measuring and test equipment, including employee- and customer-owned gauges, shall include:

- revisions following engineering changes (if appropriate),
- any out of specification readings as received for calibration/verification,
- statements of conformance to specification after calibration/verification,
- notification to the customer if suspect product or material has been shipped.

4.12 Inspection and test status

The inspection and test status of product shall be identified by suitable means, which indicate the conformance or nonconformance of product with regard to inspection and tests performed. The identification of inspection and test status shall be maintained, as defined in the quality plan and/or documented procedures, throughout production, installation and servicing of the product to ensure that only product that has passed the required inspections and tests [or released under an authorized concession (see 4.13.2)] is dispatched, used or installed.

NOTE 1 Reference to "quality plan" in 4.12 should be interpreted as "control plan".

NOTE 2 Location of product in the normal production flow does not constitute suitable indication of inspection and test status unless inherently obvious such as material in an automated production transfer process. Latitude is permitted, beyond automated production transfer processes, if the test status is clearly identified, documented, and achieves the designated purpose.

4.13 Control of nonconforming product

4.13.1 General

4.13.1.1 General – ISO 9001:1994

The supplier shall establish and maintain documented procedures to ensure that product that does not conform to specified requirements is prevented from unintended use or installation. This control shall provide for identification, documentation, evaluation, segregation (when practical), disposition of nonconforming product, and for notification to the functions concerned.

4.13.1.2 Suspect material or product

This element shall apply to suspect as well as nonconforming material or products.

The supplier shall provide visual identification for any nonconforming product, material and quarantine areas.

4.13.1.3 Corrective action plan

Suppliers shall quantify, analyse and reduce all nonconforming product by establishing a corrective action plan. Progress towards the plan shall be tracked.

Customers shall be informed promptly in the event that nonconforming product has been shipped.

4.13.2 Review and disposition of nonconforming product

The responsibility for review and authority for the disposition of nonconforming product shall be defined.

Nonconforming product shall be reviewed in accordance with documented procedures. It may be

a) reworked to meet the specified requirements,

b) accepted with or without repair by concession,

c) regraded for alternative applications, or

d) rejected or scrapped.

Where required by the contract, the proposed use or repair of product [see 4.13.2 b)] which does not conform to specified requirements shall be reported for concession to the customer or customer's representative. The description of the nonconformity that has been accepted, and of repairs, shall be recorded to denote the actual condition (see 4.16).

Repaired and/or reworked product shall be re-inspected in accordance with the quality plan and/or documented procedures.

NOTE 1 Reference to "quality plan" (4.13.2) should be interpreted as "control plan".

NOTE 2 Subclause 4.16 in ISO 9001:1994 is 4.16.1 in this Technical Specification.

4.13.3 Control of reworked product

Rework instructions shall be accessible and utilized by the appropriate personnel in their work areas.

4.13.4 Engineering approved authorization

The supplier shall obtain prior customer authorization whenever the product or process is different from that which is currently approved (see 4.2.4.11).

This applies equally to products or services purchased from subcontractors. The supplier shall concur with any requests by a subcontractor before submission to the customer. The supplier shall maintain a record of the expiration date or quantity authorized. The supplier shall also ensure compliance with the original or superseding specifications and requirements when the authorization expires. Material shipped on an authorization shall be properly identified on each shipping container.

4.14 Corrective and preventive action

4.14.1 General

4.14.1.1 General – ISO 9001:1994

The supplier shall establish and maintain documented procedures for implementing corrective and preventive action.

Any corrective or preventive action taken to eliminate the causes of actual or potential nonconformities shall be to a degree appropriate to the magnitude of problems and commensurate with the risks encountered.

The supplier shall implement and record any changes to the documented procedures resulting from corrective and preventive action.

4.14.1.2 Problem solving

The supplier shall use problem-solving methods (i.e. problem identification, containment, root cause identification, verification of effectiveness of corrective action), when an internal or external nonconformity to specification or requirement occurs. When external nonconformities occur, the supplier shall respond in a manner acceptable to the customer.

If customer-prescribed format exists, the supplier shall use the prescribed format.

4.14.1.3 Mistake-proofing

The supplier shall use mistake-proofing methods in their corrective and preventive action process to a degree appropriate to the magnitude of the problems and commensurate with the risks encountered.

4.14.2 Corrective action

4.14.2.1 Corrective action – ISO 9001:1994

The procedures for corrective action shall include:

a) the effective handling of customer complaints and reports of product nonconformities;

b) investigation of the cause of nonconformities relating to product, process and quality system, and recording the results of the investigation (see 4.16);

c) determination of the corrective action needed to eliminate the cause of nonconformities;

d) application of controls to ensure that corrective action is taken and that it is effective.

NOTE Subclause 4.16 in ISO 9001:1994 is 4.16.1 in this Technical Specification.

4.14.2.2 Corrective action impact

The supplier shall apply the corrective action taken, and controls implemented, to eliminate the cause of a nonconformity to other similar processes and products.

4.14.2.3 Returned product test/analysis

The supplier shall analyse parts returned from the customer's manufacturing plants, engineering facilities, and dealerships. The supplier shall minimize the cycle time of this process. Records of these analyses shall be kept and made available upon request. The supplier shall perform effective analysis and, where appropriate, initiate corrective action to prevent recurrence.

NOTE Cycle time should be consistent with determination of root cause, corrective action and monitoring effectiveness of implementation.

4.14.3 Preventive action

The procedures for preventive action shall include:

a) the use of appropriate sources of information such as processes and work operations which affect product quality, concessions, audit results, quality records, service reports and customer complaints to detect, analyse and eliminate potential causes of nonconformities;

b) determination of the steps needed to deal with any problems requiring preventive action;

c) initiation of preventive action and application of controls to ensure that it is effective

d) ensuring that relevant information on actions taken is submitted for management review (see 4.1.3).

NOTE Subclause 4.1.3 in ISO 9001:1994 is 4.1.3.1 in this Technical Specification.

4.15 Handling, storage, packaging, preservation and delivery

4.15.1 General

The supplier shall establish and maintain documented procedures for handling, storage, packaging, preservation and delivery of product.

4.15.2 Handling

The supplier shall provide methods of handling product that prevent damage or deterioration.

4.15.3 Storage

4.15.3.1 Storage – ISO 9001:1994

The supplier shall use designated storage areas or stock rooms to prevent damage or deterioration of product, pending use or delivery. Appropriate methods for authorizing receipt to and dispatch from such areas shall be stipulated.

In order to detect deterioration, the condition of product in stock shall be assessed at appropriate intervals.

4.15.3.2 Inventory

The supplier shall use an inventory management system to optimize inventory turns over time and assure stock rotation, such as "first in first out" (FIFO). Obsolete product shall be controlled in a similar manner to nonconforming product.

4.15.4 Packaging

4.15.4.1 Packaging – ISO 9001:1994

The supplier shall control packing, packaging and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements.

4.15.4.2 Customer packaging standards

The supplier shall comply with all customer packaging requirements, including those applicable for service parts.

4.15.4.3 Labelling

The supplier shall have a system to ensure that all materials shipped are labelled according to customer requirements.

4.15.5 Preservation

The supplier shall apply appropriate methods for preservation and segregation of product when the product is under the supplier's control.

4.15.6 Delivery

4.15.6.1 Delivery – ISO 9001:1994

The supplier shall arrange for the protection of the quality of product after final inspection and test. Where contractually specified, this protection shall be extended to include delivery to destination.

4.15.6.2 Performance monitoring of supplier delivery

The supplier shall establish systems to support 100 % on-time deliveries to meet customer production and service requirements. If 100 % on-time deliveries are not maintained the supplier shall:

- inform the customer of an anticipated delivery problem,
- implement corrective action to improve delivery performance.

The supplier shall have a systematic approach to develop, evaluate and monitor adherence to established lead time requirements. The supplier shall implement a system to monitor performance to the customer delivery requirements with corrective actions taken as appropriate. Records of supplier-responsible premium freight shall be maintained.

The supplier shall ship all product or materials in conformance with customer requirements, adhering to up-to-date customer-specified transportation mode, routings and containers.

4.15.6.3 Production scheduling

There shall be an appropriate scheduling of production to meet customer requirements, such as just in time supported by an information system that permits access to production information at the key stages of the process and is order driven.

4.15.6.4 Electronic communication

The supplier shall have a computerized system for receipt of customer planning information and ship schedules, unless another method is agreed with the customer.

4.15.6.5 Shipment notification system

The supplier shall have a computerized system for on-line transmittal of advance shipment notifications (ASNs), transmitted at the time of shipment, unless another method is agreed with the customer.

The supplier shall have a back-up method in the event that the on-line system fails. The supplier shall verify that all ASNs match shipping documents and labels.

4.16 Control of quality records

4.16.1 Control of quality records – ISO 9001:1994

The supplier shall establish and maintain documented procedures for identification, collection, indexing, access, filing, storage, maintenance and disposition of quality records.

Quality records shall be maintained to demonstrate conformance to specified requirements and the effective operation of the quality system. Pertinent quality records from the subcontractor shall be an element of these data.

All quality records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of quality records shall be established and recorded. Where agreed contractually, quality records shall be made available for evaluation by the customer or the customer's representative for an agreed period.

NOTE 1 Records may be in the form of any type of media, such as hard copy or electronic media.

NOTE 2 "Disposition" above includes disposal; "quality records" also include customer-specified records.

4.16.2 Record retention

The supplier shall define retention periods for quality system related documents and records to satisfy regulatory and customer requirements as a minimum.

4.17 Internal quality audits

4.17.1 Internal quality audits – ISO 9001:1994

The supplier shall establish and maintain documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system.

Internal quality audits shall be scheduled on the basis of the status and importance of the activity to be audited and shall be carried out by personnel independent of those having direct responsibility for the activity being audited.

The results of the audits shall be recorded (see 4.16) and brought to the attention of the personnel having responsibility in the area audited. The management personnel responsible for the area shall take timely corrective action on the deficiencies found during the audit.

Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken (see 4.16).

NOTE 1 The results of internal quality audits form an integral part of the input to management review activities (see 4.1.3).

NOTE 2 Guidance on quality system audits is given in ISO 10011.

NOTE 3 Subclauses 4.1.3 and 4.16 in ISO 9001:1994 are 4.1.3.1 and 4.16.1 respectively in this Technical Specification.

4.17.2 Internal quality audits – supplemental

4.17.2.1 General

When internal/external nonconformities or customer complaints occur, the audit frequency shall be appropriately increased.

NOTE A plan for audits should be established according to ISO 10011-1. Specific checklists should be used for each area, function or process audited.

4.17.2.2 System audit

Internal system audits shall cover all activities and shifts. System audits shall be scheduled according to an annual plan to verify compliance with this Technical Specification and any additional system requirements.

4.17.2.3 Process audit

The supplier shall audit the product realization and production processes to determine the effectiveness of process performance (see A.43).

4.17.2.4 Product audit

The supplier shall audit products at appropriate stages of production and delivery to verify conformance to all specified requirements, such as product dimensions, packaging, labelling, at an appropriate frequency (see A.47).

4.17.3 Auditor qualification

The supplier shall comply with customer requirements for internal system and process auditor qualification.

4.18 Training

4.18.1 Training – ISO 9001:1994

The supplier shall establish and maintain documented procedures for identifying training needs and provide for the training of all personnel performing activities affecting quality. Personnel performing specific assigned tasks shall be qualified on the basis of appropriate education, training and/or experience, as required. Appropriate records of training shall be maintained (see 4.16).

NOTE 1 This applies to all employees at all levels of the organization.

NOTE 2 Subclause 4.16 in ISO 9001:1994 is 4.16.1 in this Technical Specification.

4.18.2 Training effectiveness

Training effectiveness shall be periodically reviewed. Special attention shall be given on customer-specific requirements.

NOTE Training effectiveness may be reviewed by various methods, such as pre- and post-testing and audits/appraisals of performance.

4.18.3 Training on the job

The supplier shall provide on the job training for personnel in any new or modified job affecting quality, if appropriate. This includes contract or agency personnel.

Personnel affecting quality shall be informed about the consequences for the customer of nonconformities with quality standards.

4.19 Servicing

4.19.1 Servicing – ISO 9001:1994

Where servicing is a specified requirement, the supplier shall establish and maintain documented procedures for performing, verifying and reporting that the servicing meets the specified requirements.

NOTE Any after-sales product servicing provided as part of the OEM contract or purchase order would fall under element 4.19.1.

4.19.2 Feedback of information from service

A procedure for communication of information on service concerns to manufacturing, engineering and design activities shall be established and maintained.

NOTE The intent of the addition of "service concerns" to element 4.19 is to ensure that the supplier's organization is aware of nonconformities that occur external to the supplier's own organization (see 4.14).

4.19.3 Servicing agreement with customer

When there is a servicing agreement with the customer, the supplier shall verify the effectiveness of:

- any supplier service centres,
- special purpose tools,
- training of servicing personnel.

4.20 Statistical techniques

4.20.1 Identification of need

The supplier shall identify the need for statistical techniques required for establishing, controlling and verifying process capability and product characteristics.

4.20.2 Procedures

The supplier shall establish and maintain documented procedures to implement and control the application of the statistical techniques identified in 4.20.1.

4.20.3 Identification of statistical tools

Appropriate statistical tools for each process shall be determined during advance quality planning and included in the control plan.

4.20.4 Knowledge of basic statistical concepts

Basic concepts, such as variation, control (stability), process capability and over-adjustment shall be understood throughout the supplier's organization as appropriate (see for example bibliography [13], [21], [22], [40], [41]).

Annex A
(normative)
Terms and definitions

A.1
accredited laboratory
laboratory that has been reviewed and approved by a nationally recognized accreditation body

EXAMPLE American Association for Laboratory Accreditation (A2LA) or Comité Français d'Accréditation (COFRAC) for test laboratory accreditation to ISO/IEC 17025 or national equivalent.

A.2
advance shipment notification
ASN
notification from a company to its customer, normally via electronic media in the customer's format

A.3
benchmarking
technique to determine best practice

A.4
business plan
plan approved by executive management that contains goals, objectives and measurements for the organization, including quality

A.5
CAD
computer-aided design
computer system capabilities that automate the creation and editing of geometry, dimensions and other drafting annotations which allow a user to define the shape and physical characteristics of an object

A.6
CAE
computer-aided engineering
use of computer technology to aid in the engineering process

NOTE These aids can produce engineering analysis data sometimes used for simulation and finite element analysis.

A.7
calibration
set of operations which establish, under specific conditions, the relationship between values indicated by a measuring system, or values represented by a material measure or reference material, and the corresponding values of a quantity realized by a reference standard

A.8
contingency plan
plan to overcome unexpected situations (utility interruptions, labour shortages or key equipment failure) in order to maintain product supply

A.9
continuous improvement plan/programme
plan or programme for the optimization of characteristics and parameters of a product or process at a target value

NOTE Continuous improvement is only applicable where conformance has been established.