Technical Specification **ISO/TS** 16949
Second Edition 2002-03-01

Original draft 1 send on January 29 including :
Differences between FDIS and ISO 9000 :2000 (additions in blue bold)
ITALIAN remarks (except the replacements of supplier by organization)
FRENCH remarks
AMERICAN remarks
ENGLISH remarks

Quality systems Automotive suppliers Particular requirements for the application of ISO9001:2000

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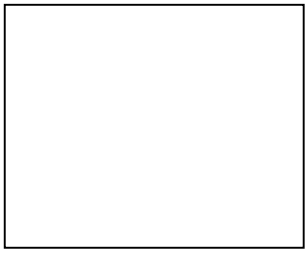

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Technical Specification **ISO/TS** 16949

Second Edition 2002-03-01

FRA : ISO nd edition

Each national IATF and national standard organization is to be seen after
This original one is the model of the AIAG edition of the TS 1st edition

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Quality management systems Automotive suppliers Particular requirements for the application of ISO9001:2000

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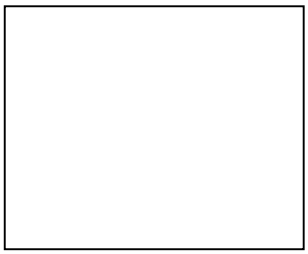

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FRA : ISO copyright notice to be reviewed

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UK NEED TO RESOLVE THIS ISSUE AND AS A MINIMUM INCLUDE SMMT IF IT REMAINS

UK - SMMT

FRA : to be reviewed: responsibles and adresses may be different

FRA : foot note to be reviewed

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Foreword TS 1st

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ISO/CEN PARALLEL PROCESSING

Contents

ISO headings are normal type face, *IATF headings are in italics*

FRA : contents shall be established after completion

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.

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.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights.

ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 9001 was prepared by Technical Committee ISO/TC 176, Quality management and Quality assurance,Subcommittee SC 2, Quality systems.

This third edition of ISO 9001 cancels and replaces the second edition (ISO 9001:1994) together with ISO 9002:1994 and ISO 9003:1994. It constitutes a technical revision of these documents. Those organizations Which have used ISO 9002:1994 and ISO 9003:1994 in the past may use this International Standard by excluding certain requirements in accordance with 1.2. **(Note:rewording required)**

USA : foot note to be reviewed

This reflects the fact that the quality management system requirements specified in this edition of ISO 9001, in addition to quality assurance of product, also aim to enhance customer satisfaction.

Annexes A and B of this International Standard are for information only.

FRA : TS 1st Foreword below TO BE ADAPTED AND INCLUDED

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.

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FRA: foreword to be reviewed by ISO according the status of the TS 2nd
Annexes status to be defined, IATF foreword to write (remark for certification, adresses of national

Introduction

0.1 General

The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

The quality management system requirements specified in this International Standard are complementary to

associated requirement.

This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, regulatory and the organization's own requirements.

The quality management principles stated in **ISO 9000 and** ISO 9004 have been taken into consideration during the development of this International Standard.

0.2 Process approach

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

For an organization to function effectively, it has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these proce

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

When used within a quality management system, such an approach emphasizes the importance of

a) understanding and fulfilling requirements,

b) the need to consider processes in terms of added value,

c) obtaining results of process performance and effectiveness, and

d) continual improvement of processes based on objective measurement.

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.

-Do-Check-

PDCA can be briefly described as follows.

Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies.

Do: implement the processes.

Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

Act: take actions to continually improve process performance.

Figure 1 Model of a process-based quality management system

(ISO 9001 : 2000 page vii)

ITA : Use of quality management principles

0.3 Compatibility with other management systems

This International Standard has been aligned with ISO 14001:1996 in order to enhance the compatibility of the two standards for the benefit of the user community.

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

0.4 Goal of ISO/TS16949:2000

The goal of this Technical Specification is the development of a quality management system that provide for continual improvement, emphasizing defect prevention and the reduction of variation and waste in the supply

chain. This Technical Specification defines the quality management system requirements for the automotive industry. It is recognized that there may be customer-specific requirements that apply,.

This Technical Specification is intended to avoid multiple certification audits and provide a common automotive approach to quality management..

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Quality management systems Requirements

1 Scope

1.1 General

This International Standard specifies requirements for a quality management system where an organization

a) needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and

~~c)~~b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.

by, a customer.

This Technical Specification, in conjunction with ISO 9001:2000, defines the quality management system requirements for the design/development, production and, when relevant, installation and servicing of automotive-related products

This Technical Specification is applicable to sites where customer specified products are manufactured.

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

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

1.2 Application

All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion.

Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that fulfils **meets** customer and applicable regulatory requirements.

Design responsible organization shall not exclude product design and development from the scope of the certification. Manufacturing process design shall not be excluded.

2 Normative reference

The following normative document contains provisions, which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document 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 9000 **: 2000**, Quality management systems Fundamentals and vocabulary.

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 9000 apply.

The following terms, used in this edition of ISO 9001 to describe the supply chain, have been changed to reflect the vocabulary currently used:

Supplier ⟶ organization ⟶ customer

rs, it can also mean

3.1 Highlighted automotive terms

For the purposes of this Technical Specification the terms and definitions given in ISO 9000 :2000 and in annex A apply. However where there are terms for which the wording of the definition differs in ISO 9000 :2000, the definitions in annex A apply.

Product

Organization

Supplier / sub-contractor

Outsourcing

Document

Process

DesignProduct realizationPurchased product

4 Quality management system

4.1 General requirements 4.2.1

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The organization shall

a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2),

~~c)~~b) determine the sequence and interaction of these processes,

~~e)~~c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,

~~g)~~d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,

~~i)~~e) monitor, measure and analyse these processes, and

~~k)~~f) implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the organization in accordance with the requirements of this International Standard.

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.

NOTE Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.

NOTE 1 When the organization subcontracts, the organization cannot delegate the technical responsibility.

4.2 Documentation requirements

4.2.1 General 4.2.2.1 4.2.2.2

The quality management system documentation shall include

a) documented statements of a quality policy and quality objectives,

~~c)~~b) a quality manual,

e)c)documented procedures required by this International Standard,

g)d)documents needed by the organization to ensure the effective planning, operation and control of its processes, and

i)e)records required by this International Standard (see 4.2.4).

the procedure is established, documented, implemented and maintained.

NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to

a) the size of organization and type of activities,

c)b)the complexity of processes and their interactions, and

e)c)the competence of personnel.

NOTE 3 The documentation can be in any form or type of medium.

***NOTE:* ISO/TS 16949 specifies additional documentation requirements (parking lot)**

4.2.2 Quality manual 4.2.1

The organization shall establish and maintain a quality manual that includes

a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2),

c)b)the documented procedures established for the quality management system, or reference to them, and

e)c)a description of the interaction between the processes of the quality management system.

4.2.3 Control of documents 4.5.1 4.5.2.1 4.5.2.2 4.5.3

Documents required by the quality management system shall be controlled. Quality records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

a) to approve documents for adequacy prior to issue,

c)b)to review and update as necessary and re-approve documents,

e)c)to ensure that changes and the current revision status of documents are identified,

g)d)to ensure that relevant versions of applicable documents are available at points of use,

i)e) to ensure that documents remain legible and readily identifiable,

k)f) to ensure that documents of external origin are identified and their distribution controlled, and

m)g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.3.1 Engineering specifications

The organization shall have a process to assure the timely review, distribution and implementation of all customer engineering standards/specifications and changes based on customer required schedule. The organization shall maintain a record of the date on which each change is implemented in production. Implementation shall include updates documents.

4.2.4 Control of records 4.16.1 4.16.2

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

NOTE 1 "Disposition" above includes disposal.

NOTE 2 "Quality records" also include customer-specified records.

4.2.4.1 Records retention

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

5 Management responsibility

5.1 Management commitment 4.1.1.1

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,

c)b) establishing the quality policy,

e)c) ensuring that quality objectives are established,

g)d) conducting management reviews, and

i)e) ensuring the availability of resources.

5.1.1 Process oriented organization

Top management shall identify the product realization processes, that provide added value to the organization, and the support processes that affect the effectiveness and efficiency of the realization processes (parking lot)

5.2 Customer Focus

Top management shall ensure that customer requirements are determined and fulfilled with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).

5.3 Quality policy 4.1.1.1 4.1.1.4

Top management shall ensure that the quality policy

a) is appropriate to the purpose of the organization,

c)b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,

e)c) provides a framework for establishing and reviewing quality objectives,

g)d) is communicated and understood within the organization, and

i)e) is reviewed for continuing suitability.

5.3.1 Quality policy supplemental

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

5.4 Planning

ITA : ~~5.4 Planning~~

5.4.1 Quality objectives **4.1.1.2**

Top management shall ensure that quality objectives, including those needed to meet requirements for product (see 7.1) are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

5.4.1.1 Quality objectives - supplemental

Top management shall define quality objectives and measurements in the business plan to deploy the quality policy.

5.4.2 Quality management system planning **4.2.3.1**

Top management shall ensure that

a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and

~~c)~~b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority **4.1.2.1 4.1.2.1.3**

Top management shall ensure that the responsibilities **and** authorities are defined and communicated within the organization.

5.5.1.1 Quality responsibility

Management with responsibility and authority for corrective action shall be promptly informed of products or processes which do not comply with requirements.

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

Production operations across all shifts shall be staffed with personnel in charge of, or delegated responsibility for assuring product quality.

5.5.2 Management representative **4.1.2.1.2 4.1.2.1.3**

Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes

a) ensuring that processes needed for the quality management system are established, implemented and maintained,

c)b) reporting to top management on the performance of the quality management system and any need for improvement, and

e)c) ensuring the promotion of awareness of customer requirements throughout the organization.

NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

5.5.2 1 Customer representative

Top management shall designate individual(s) to represent the needs of the customer to address quality requirements, such as selection of special characteristics, setting quality objectives and relatedtraining, corrective and preventive actions, product design and development.

5.5.3 Internal communication

Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management review

5.6.1 General **4.1.3.1 4.1.3.2 4.2.8**

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained (see 4.2.4).

5.6.1.1 Quality management system performance

These reviews shall include all elements of the quality system and its performance trends as an essential part of the continual improvement process.

Part of the management review shall be the monitoring of quality objectives, and the regular reporting and evaluation of the cost of poor quality (see 8.4.1).

These results shall be recorded to provide, as a minimum, evidence of the achievement of:

a) Objectives specified in the quality policy;

c)b)Objectives specified in the business plan;

e)c)customer satisfaction with product supplied.

NOTE : To ensure accurate evaluation of the data, use of-
should be utilized. (parking lot - find an other place)

5.6.2 Review input

The input to management review shall include information on

a) results of audits,

c)b)customer feedback,

e)c)process performance and product conformity,

g)d)status of preventive and corrective actions,

i)e)follow-up actions from previous management reviews,

k)f)planned changes that could affect the quality management system, and

m)g)recommendations for improvement.

5.6.2.1 Review input - Supplemental

Analysis of field-failures and their impact on quality, safety, or the environment shall be input to management review

5.6.3 Review output

The output from the management review shall include any decisions and actions related to

a) improvement of the effectiveness of the quality management system and its processes,

c)b)improvement of product related to customer requirements, and

e)c)resource needs.

NOTE: Results of management review should be classified as requiring either corrective, or improvement action.

6 Resource management

6.1 Provision of resources 4.1.2.2.1 4.4.2.3

The organization shall determine and provide the resources needed

a) to implement and maintain the quality management system and continually improve its effectiveness, and

c)b) to enhance customer satisfaction by meeting customer requirements.

6.2 Human resources

6.2.1 General 4.1.2.2.2

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, awareness and training 4.4.2.2 4.18/1/2/3 4.1.6

The organization shall

a) determine the necessary competence for personnel performing work affecting product quality,

c)b) provide training or take other actions to satisfy these needs,

c)c) evaluate the effectiveness of the actions taken,

g)d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and

i)e) maintain appropriate records of education, training, skills and experience

6.2.2.1 Product design skills

The organization shall ensure that personnel with product design responsibility are qualified to achieve design requirements and skilled in applicable tools and techniques.

– Applicable tools and techniques shall be identified by the organization

6.2.2.2 Training

The organization shall establish and maintain documented procedures for identifying training needs and achieving competence of all personnel performing activities affecting quality. Personnel performing specific assigned tasks shall be qualified on the basis of education, training, skills and/or experience, as required. Records of training shall be maintained. Special attention shall be given to satisfying customer-specific requirements.

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

Note 2 An example of the customer specific requirements is the application of digitized math-based data.

6.2.2.4 Training on the job

The organization shall provide on the job training for personnel in any new or modified job affecting product quality including contract or agency personnel. Personnel affecting quality shall be informed about the consequences to the customer of non-conformance to quality requirements.

6.2.2.5 Employee motivation, empowerment and satisfaction

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

The organization shall have a process for measurement to ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives (see 6.2.2 d) .

6.3 Infrastructure 4.9.1.1 4.9.1.3

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable

a) buildings, workspace and associated utilities,

c)b)process equipment,(both hardware and software), and

e)c)supporting services (such as transport or communication).

6.3.1 Plant, facility and equipment planning

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

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

- **operator and line balance,**
- **storage and buffer inventory levels,**
- **value-adding content.**

6.3.2 Contingency plans

The organization shall prepare contingency plans, to satisfy the customer specified requirements in the event of an emergency such as utility interruptions, labour shortages, or key equipment failure.

6.4 Work environment 4.1.7.1 4.9.1.2

The organization shall determine and manage the work environment needed to achieve conformity to product requirements.

6.4.1 Safety

Due care regarding product safety and means to minimize potential risks to employees shall be addressed in the organization's quality policy and practices, especially in design control and process control procedures and practices. The organization shall promote internal awareness of safety considerations related to the

6.4.2 Cleanliness of premises

The organization shall maintain its premises in a state of order cleanliness and repair consistent with the product.

6.5 Sourcing

The organization shall identify qualified sources of supply needed to realize products. To maintain consistency and stability, sourcing shall include a process to manage supplier communication and improvement.

7 Product realization

7.1 Planning of product realization 4.2.3.2 4.2.4.1

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).

In planning product realization, the organization shall determine the following, as appropriate:

a) quality objectives and requirements for the product;

~~c)~~b) the need to establish processes, documents, and provide resources specific to the product;

~~e)~~c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;

~~g)~~d) records needed to provide evidence that the realization processes and resulting product fulfil **meet** requirements (see 4.2.4).

The output of this planning shall be in a form suitable for the organization's method of operations.

NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.

NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.

NOTE 3 Some customers refer to project management or advance quality planning as a means to achieve product realization. Quality planning embodies the concepts of error prevention and continual improvement as contrasted with error detection and is based on a multidisciplinary approach.

7.1.1 Quality plan requirements

The organization shall have a quality plan which includes customer requirements and references to technical specifications.

7.1.2 Change control

The organization shall have a process to control and react to changes that impact product realization. The effects of any change shall be assessed, and verification and validation activities shall be defined, to ensure compliance with customer requirements. Changes shall be validated before implementation.

NOTE : Any change requires notification to, and agreement from the customer.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product 4.1.7.1 4.1.7.2 4.9.1.4

The organization shall determine

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,

c)b) requirements not stated by the customer but necessary for specified **or intended use, where known,**

e)c) statutory and regulatory requirements related to the product, and

g)d) any additional requirements determined by the organization.

NOTE 1 : This require

knowledge of the product and manufacturing processes (See 7.3.2.3).

Note 2 : Compliance to item c) includes all applicable government, safety and environmental regulations, applied to acquisition, storage, handling, recycling, elimination or disposal of materials.

7.2.1.1 Customer designated special characteristics

The organization shall demonstrate conformity to customer requirements for designation, documentation and control of special characteristics.

7.2.2 Review of requirements related to the product 4.2.4.8 4.3.1 4.3.2.1 4.3.3 4.3.4 4.3.2.2 4.2.4.6

The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that

a) product requirements are defined,

c)b) contract or order requirements differing from those previously expressed are resolved, and

e)c) the organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertizing material.

NOTE : Waiver to the formal review in the above note requires customer authorization.7.2.2.1 Manufacturing feasibility

The organization shall investigate, confirm and document the manufacturing feasibility of the proposed products in the contract review process including risk analysis .

7.2.3 Customer communication 4.1.2.4

The organization shall determine and implement effective arrangements for communicating with customers in relation to

a) product information,

c)b)enquiries, contracts or order handling, including amendments, and

c)c)customer feedback, including customer complaints.

7.2.3.1 Customer communication - supplemental

The organization shall have the ability to communicate necessary information including data in a customer specified language and format, (e.g. computer-

7.3 Design and development

IMPORTANT : The requirements of element 7.3 include product and manufacturing process design and development, and should focus on error prevention rather than detection.

7.3.1 Design and development planning 4.1.2.4 4.4.1 4.4.2.1 4.4.3 4.2.4.9.1

The organization shall plan and control the design and development of product.

During the design and development planning, the organization shall determine

a) the design and development stages,

c)b)the review, verification and validation that are appropriate to each design and development stage, and

c)c)the responsibilities and authorities for design and development.

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

Note : Error prevention is driven by Simultaneous Engineering performed by product engineering and manufacturing engineering activities working concurrently. (parking lot)

7.3.1.1 Multidisciplinary approach

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

- development/ finalization and monitoring of special characteristics,
- development, and review of FMEAs including actions to reduce potential risks,
- development, and review of control plans.

7.3.2 Design and development inputs **4.4.4.1 4.4.4.3 4.2.4.9.2 4.2.4.7 4.4.2.2**

Inputs relating to product requirements shall be determined and records maintained (see 4.2.4).

These **inputs** shall include

a) functional and performance requirements,

~~c)~~b) applicable statutory and regulatory requirements,

~~e)~~c) where applicable, information derived from previous similar designs, and

~~g)~~d) other requirements essential for design and development.

These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

Note: Special characteristics (ref 7.2.1.1) are included in this requirement.

7.3.2.1 Product design input :

The organization shall identify, document and review the product design inputs requirements including :

- Customer requirements (contract review) such as special characteristics (see 7.3.2.3), identification, traceability packaging, ...
- use of information : The organization shall have a process to deploy information gained from previous design projects, competitor analysis, supplier feedback, internal input, field data, and other relevant sources, for current and future projects of a similar nature.
- targets for product quality, life, reliability, durability, maintainability, timing, cost, ...

7.3.2.2 Manufacturing process design input

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

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

7.3.2.3 Innovation

The organization shall have a process for innovation in product and process . (parking lot)

7.3.2.4 Special characteristics

The organization shall identify special characteristics (see 7.3.3 d)). (see annex C).

All special characteristics shall be included in the control plan.

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

Process control documents such as FMEAs, control plans and operator instructions shall be marked with the customer's special characteristics.

NOTE Special characteristics may include product characteristics and process parameters.

7.3.3 Design and development outputs 4.4.5.1 4.2.4.9.3 4.4.5.2

The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

Design and development outputs shall

a) meet the input requirements for design and development,

b) provide appropriate information for purchasing, production and for service provision,

c) contain or reference product acceptance criteria, and

d) specify the characteristics of the product that are essential for its safe and proper use.

7.3.3.1 Product design outputs - Supplemental

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

- Design FMEA, reliability results
- Product special characteristics, specifications,
- Product mistake-proofing, as appropriate,
- Product definition including drawings,
- Product design reviews results,

The organization's design output shall be the result of an optimization process.

NOTE This optimization process should include,:

- 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 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,

7.3.3.2 Manufacturing process design output

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

- specifications and drawings,
- manufacturing process flow chart / layout
- manufacturing process FMEAs,
- control plan (see 7.5.1.1.)
- work 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 non-conformities

7.3.4 Design and development review 4.2.4.3 4.4.6 4.1.2.4 4.2.4.4

At suitable stages, systematic reviews of design and development shall be conducted **performed in accordance with planned arrangements (see 7.3.1)**

a) to evaluate the ability of the results of design and development to fulfil requirements, and

~~c)~~b) to identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).

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

7.3.4.1 Monitoring

Measurements at specified stages of design and development shall be defined, analyzed and reported with summary results as an input to management review.

NOTE These measurements include quality risks, costs, lead-times, critical paths and others, as appropriate.

7.3.5 Design and development verification 4.2.4.9.4 4.4.7

Verification shall be performed **in accordance with planned arrangements (see 7.3.1)** to ensure that the design and development outputs have satisfied the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).

7.3.6 Design and development validation 4.2.4.11 4.4.8.1 4.4.8.2 4.4.8.3

Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of fulfilling **meeting** the requirements for the specified or known intended use or application **or intended use**. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).

NOTE: The validation process should include an analysis of field reports.

7.3.6.1 Design and development validation supplemental

Design validation shall be performed in conjunction with customer program timing requirements.

(records of design failures and corrective actions)

7.3.6.2 Prototype program

When required by the customer, the organization shall have a prototype program and a prototype control plan. The organization shall use, wherever possible, the same suppliers, tooling and manufacturing 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 organization shall provide technical leadership.

7.3.6.3 Product approval process

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

NOTE 1 Product approval is the final step of this procedure after the manufacturing process is verified.

This product and manufacturing process approval procedure shall also be applied to suppliers.

7.3.7 Control of design and development changes 4.2.4.11 4.4.9.1 4.4.9.2

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and **already** delivered product.

Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).

NOTE Design and development changes include all changes during the life cycle of the product.

7.3.7.1 Control of design and development changes - supplemental

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

The organization 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.

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

NOTE : See 7.1.2

7.4 Purchasing

7.4.1 Purchasing process 4.6.1.1 4.6.2.1/2/3 4.6.1.2 4.6.1.3

The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization shall evaluate and select suppliers based on their ability to supply products in accordance with requirements. Criteria for selection, evaluation, and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see4.2.4)

NOTE 1 : Purchased products above includes all products and services that impact customer requirements such as sorting, rework and calibration services.

NOTE 2 Where there are mergers, acquisitions, or affiliations associated with suppliers, the organization should, verify the continuity of the su

7.4.1.2 Regulatory compliance

All purchased products or materials used in part manufacture shall satisfy current applicable regulatory requirements.

7.4.1.3 Supplier quality management system development

The organization shall perform supplier quality management system development with the goal of compliance to this Technical Specification. As a minimum the supplier shall be compliant with ISO 9001 : 2000 .

Note 1: Supplier compliance can be verified as a result of first party or second party audit, or third-party certification. Such compliance is not intended to limit more specific supplier quality development.

7.4.1.4 Customer-approved sources

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

The use of customer-designated sources, including tool/gage suppliers, does not relieve the organization of the responsibility for ensuring the quality of purchased products .

7.4.2 Purchasing information 4.6.3

Purchasing information shall describe the product to be purchased, including where appropriate

a) requirements for approval of product, procedures, processes and equipment,

~~c)~~b) requirements for qualification of personnel, and

~~e)~~c) quality management system requirements.

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 Verification of purchased product 4.6.4.1 4.6.4.2

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

7.5 Production and service provision

7.5.1 Control of production and service provision 4.9.1.1 4.9.1.5 4.9.2 4.2.4.10 4.19.1 4.19.2 4.19.3 4.2.5 4.2.6 4.9.4 4.9.5 4.15.6.2 4.15.6.3

The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable

a) the availability of information that describes the characteristics of the product,

~~c)~~b) the availability of work instructions, **as necessary,**

~~e)~~c) the use of suitable equipment,

~~g)~~d) the availability and use of monitoring and measuring devices,

~~i)~~e) the implementation of monitoring and measurement, and

~~k)~~f) the implementation of release, delivery and post-delivery activities.

NOTE Post-delivery activities mean any after-sales product servicing provided as part of the customer contract or purchase order.

7.5.1.2 Control plan

The organization shall:

- develop control plans at the system, subsystem, component and/or material level, for the product supplied,
- have a control plan for pre-launch and production that take into account the Design FMEA and Process FMEA outputs,
- use a multidisciplinary approach to develop control plans,
- list on the control plan the controls used for process control ,
- include the customer required information on the control plan (see annex B),
- initiate the specified reaction plan .

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 as a minimum, shall include methods for monitoring and recording results of control exercised over special characteristics (see 7.3.2.3) defined by both the customer and the organization.

Control plans shall be reviewed and updated 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.

7.5.1.3 Work instructions

The organization shall prepare documented work instructions for all employees having responsibilities for the operation of processes. These instructions shall be accessible for use at the work-station.

These instructions shall be derived from sources such as the quality plan, the control plan and the product realization process.

7.5.1.4 Verification of job set-ups

Job set-ups shall be verified whenever performed, such as an initial run of a job, material changeover, job change.

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

NOTE Last-off-part comparisons are recommended.

7.5.1.5 Preventive and predictive maintenance

The organization shall identify key process equipment and provide resources for machine/equipment maintenance and develop an effective planned total preventive maintenance system . 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,

The organization shall utilize predictive maintenance methods to maximize the effectiveness and the efficiency of production equipment.

NOTE : Inputs may include items such as the manu
correlation of SPC data to preventive maintenance activities, important characteristics of perishable tooling, fluid analysis, infrared monitoring of circuits and vibration analysis.

7.5.1.6 Tooling management

The organization shall provide resources for tool and gauge design, fabrication and verification activities.

The organization 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,
- tooling identification defining the status, such as production, repair or disposal.

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

NOTE This requirement also applies to tooling availability for vehicle service parts.

7.5.1.7 Production scheduling

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

7.5.1.8 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 this element is to ensure that the organization is aware of nonconformities that occur external of its own organization.

7.5.1.9 Servicing agreement with customer

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

- any organization service centres,
- special purpose tools or measurement equipment,
- training of servicing personnel.

7.5.2 Validation of processes for production and service provision 4.9.1.1

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

The organization shall establish arrangements for these processes including, as applicable

a) defined criteria for review and approval of the processes,

~~c)~~b) approval of equipment and qualification of personnel,

~~e)~~c) use of specific methods and procedures,

~~g)~~d) requirements for records (see 4.2.4), and

~~i)~~e) revalidation.

NOTE This element applies to all processes for production and service provision.

7.5.3 Identification and traceability 4.8 4.12

Where appropriate, the organization shall identify the product by suitable means throughout product realization.

The organization shall identify the product status with respect to monitoring and measurement requirements.

Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4).

NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.

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

NOTE 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.

7.5.4 Customer property 4.7.1 4.7.2

The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.4).

NOTE Customer property can include intellectual property.

NOTE Customer-owned returnable packaging is included in this element .

7.5.4.1 Customer owned tooling

Customer-owned tools, manufacturing, test, inspection tooling and equipment shall be permanently marked so that the ownership of each item is visible .

7.5.5 Preservation of product 4.15.1 4.15.2 4.15.3.1/2 4.15.4.1/2/3 4.15.5 4.15.6.1

The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

7.5.5.1 Storage and inventory

In order to detect deterioration, the condition of product in stock shall be assessed at appropriate planned intervals (i.e. : security storage, ...).

The organization 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.

7.6 Control of monitoring and measuring devices 4.11.1.1/2 4.11.2/3 4.10.6

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).

The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall

a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;

~~c)~~b) be adjusted or re-adjusted as necessary;

~~e)~~c) be identified to enable the calibration status to be determined;

~~g)~~d) be safeguarded from adjustments that would invalidate the measurement result;

~~i)~~e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment

and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

NOTE See ISO 10012-1 and ISO 10012-2 for guidance.

NOTE 2 : A number traceable to the device calibration record meets the intent of this requirement .

7.6.1 Measurement system analysis

Statistical studies shall be conducted to analyze 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. The analytical methods and acceptance criteria used shall conform to those in customer reference manuals on measurement systems analysis

Note : Without customer requirements, apply international standards defined in the NOTE of ISO 9001: 2000 clause 7.6 .5.

7.6.2 Calibration Records

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

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

7.6.4 Laboratory requirements

7.6.4.1 Internal laboratory

in the quality system and shall comply with technical requirements including :

- adequacy of the laboratory procedures,
- qualifications of the laboratory personnel conducting tests,
- testing of the commodity (ies) ,
- performing these tests correctly, to the relevant process standard (e.g. ASTM) and,
- review of the related quality records.

NOTE Accreditation to ISO/IEC 17025 may be used to demonstrate supplier in-house laboratory compliance to this requirement but is not mandatory.

7.6.4.2 External laboratory

External/commercial/independent laboratory facilities used for inspection, test or calibration services by the organization shall :

- be accredited to ISO/IEC 17025 or national equivalent, or
- have evidence that the external laboratory is acceptable to the customer.

NOTE 1 Such evidence may be demonstrated by e.g. : by customer assessment or by customer approved second party assessment that the laboratory meets the intend of ISO/IEC 17025 or national equivalent.

NOTE 2: Where a qualified laboratory is not available for a given piece of equipment, calibration services may be performed by the original equipment manufacturer. In such cases, the organization should ensure that the requirements above have been met

8 Measurement, analysis and improvement

8.1 General 4.20.1/2/3/4

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed

a) to demonstrate conformity of the product,

~~c)~~b) to ensure conformity of the quality management system, and

~~e)~~c) to continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

8.1.1. Identification of statistical tools

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

8.1.2. Knowledge of basic statistical concepts

Basic concepts, such as variation, control (stability), process capability and over-adjustment shall be understood throughout the organization

8.2 Monitoring and measurement

8.2.1 Customer satisfaction 4.1.1.3

As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has **met** customer requirements. The methods for obtaining and using this information shall be determined.

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

8.2.1.1 Customer satisfaction - Supplemental

Customer satisfaction with the organization shall be monitored through continual evaluation of performance of the realization processes. Performance indicators shall be based on objective data and include, but not be limited to :

- Delivered part quality performance,
- Customer disruptions including field failures,
- Delivery schedule performance (including incidents of premium freight),
- Special status customer notifications related to quality or delivery issues.

requirements for product quality and efficiency of the process.

NOTE : Indicators relating to efficiency may include results from lean manufacturing techniques, use of error-proofing devices, visual controls and feedback, use of standardized operations.

8.2.2 Internal audit **4.17.1 4.172.2/3/4 4.17.3**

The organization shall conduct internal audits at planned intervals to determine whether the quality management system

a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and

c)b)is effectively implemented and maintained.

An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.

The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

NOTE See ISO 10011-1, ISO 10011-2 and ISO 10011-3 for guidance.

8.2.2.1. Internal audit plans

Internal audits shall cover all activities and shifts.

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

NOTE Specific checklists should be used for each area, function or process audited.

8.2.2.2 Quality management system audit

Quality management system audit shall be scheduled according to an annual plan to verify compliance with this Technical Specification and any additional quality management system requirements.

NOTE

8.2.2.3 Manufacturing process audit

The organization shall audit the manufacturing processes to determine their effectiveness.

8.2.2.4 Product audit

The organization shall audit products at appropriate stages of production and delivery to verify conformance to all specified requirements, such as product dimensions, functionality, packaging, labeling, at an appropriate frequency .

8.2.2.2. Internal auditor qualification

The organization shall comply with ISO 10011-2 standard unless otherwise specified by customer requirements for internal system and process auditor qualification.

8.2.3 Monitoring and measurement of processes **4.9.3 4.2.4.5**

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.

8.2.3.1 Monitoring and measurement of processes - Supplemental

The organization shall perform process studies on all new manufacturing 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 manufacturing process capability, reliability, maintainability and availability, as well as acceptance criteria.

The organization shall maintain manufacturing process capability or performance as specified by the customer part approval process requirements. The organization shall ensure that the control plan and process flow diagram are implemented, including adherence to the specified

- measurement techniques,
- sampling plans,
- acceptance criteria,
- reaction plans when acceptance criteria are not met.

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

The organization 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 organization, indicating specific timing and assigned responsibilities to assure that the process becomes stable and capable. The plans shall be reviewed with and approved by the customer when so required.

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

8.2.4 Monitoring and measurement of product 4.10.1.1/2 4.10.2 4.10.2.4 4.10.3 4.10.4.2 4.10.5

The organization shall monitor and measure the characteristics of the product to verify that product requirements **have been met**. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1).

Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4).

Product release and service delivery shall not proceed until all the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer.

NOTE : When selecting measurement methods for ensuring that products conform to requirements and when considering customer needs and expectations, the organization should consider the types of product characteristics, which then determine the types of measurement, suitable measurement means, the capability required and skills needed (parking lot - need two sentences).

8.2.4.1. Acceptance criteria

Acceptance criteria shall be defined by the customer and documented by the organization.

8.2.4.2. Incoming product quality

The organization shall have a process to assure the quality of purchased product (see 7.4.3).

Where objective evidence of conformity to requirements does not exist, corrective action shall be implemented in conjunction with the use of one or more of these controls, or a method agreed with the customer: :

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

8.2.4.3 Supplier monitoring

Supplier performance shall be monitored through the following indicators :

- Delivered part quality performance,
- Customer disruptions including field failures,
- Delivery schedule performance (including incidents of premium freight),
- Special status customer notifications related to quality or delivery issues.

NOTE : Indicators relating to efficiency may include results from lean manufacturing techniques, use of error-proofing devices, visual controls and feedback, use of standardized operations.

8.2.4.3. 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.

8.2.4.4 Appearance items

For organizations manufacturing parts designated by the customer as "appearance items", the organization shall provide:

- appropriate lighting for evaluation areas,
- masters for color, 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.

8.3 Control of nonconforming product 4.13.1.1/2/3 4.13.2 4.13.3 4.13.4

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.

The organization shall deal with nonconforming product by one or more of the following ways:

a) by taking action to eliminate the detected nonconformity;

c)b)by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;

e)c)by taking action to preclude its original intended use or application.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.

IMPORTANT : Nonconforming includes material of unknown or suspect status

8.3.1 Customer information

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

8.3.2 Control of reworked product

Rework instructions shall be accessible and utilized by the appropriate personnel.

8.3.3. Customer authorization

The organization shall obtain customer authorization prior to changing customer-approved product or processes .

The organization shall maintain a record of the expiration date or quantity authorized. The organization 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

This applies equally to purchased products s. The organization shall agree with any requests from suppliers before submission to the customer.

8.4 Analysis of data 4.1.5

The organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement **of the effectiveness** of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to

a) customer satisfaction (see 8.2.1),

~~c)~~b) conformance to product requirements (see 7.2.1),

~~e)~~c) characteristics and trends of processes and products including opportunities for preventive action, and

~~g)~~d) suppliers.

8.4.1. Analysis and use of company level data

Trends in data and information shall be compared with progress toward quality 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.

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

8.5 Improvement

8.5.1 Continual improvement 4.1.1.4 4.2.7

The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

Note;

Examples of inputs to support the improvement process include information derived from:

- validation data,
- process yield data

– test data,
– data from self-assessment
– stated requirements and feedback from customers,
– experience of people in the organization,
– financial data including cost of poor quality
– product performance data, and
– service delivery data.

8.5.1.1. Organization continual improvement

The organization shall define a process for continual improvement (see annex B of ISO 9004 :2000).

8.5.1.2. Manufacturing process improvement

Continual improvement shall focus upon control of characteristics and reduction of variation in products and processes

NOTE 1 The control plan is a key element in monitoring and documenting improvement efforts.

NOTE 2 Continual improvement is implemented once processes are capable and stable or product characteristics are predictable and meet customer requirements.

8.5.2 Corrective action **4.14.1.1/2/3 4.14.2.1/2/3**

The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for

a) reviewing nonconformities (including customer complaints),

~~c)~~b)determining the causes of nonconformities ,

~~e)~~c)evaluating the need for action to ensure that nonconformities do not recur,

~~g)~~d)determining and implementing action needed,

~~i)~~e)records of the results of action taken (see 4.2.4), and

~~k)~~f)reviewing corrective action taken.

8.5.2.1. Problem solving

The organization shall have a defined process for problem-solving leading to root cause identification and elimination.

If a customer-prescribed problem solving format exists, the organization shall use the prescribed format.

8.5.2.2 Mistake-proofing

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

8.5.2.3. Corrective action impact

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

8.5.2.4. Rejected product test/analysis

The organization shall analyze parts rejected by the customer's manufacturing plants, engineering facilities, and dealerships. The organization shall minimize the cycle time of this process. Records of these analyses shall be kept and made available upon request. The organization shall per form analysis and, , initiate corrective action to prevent recurrence.

NOTE Cycle time related to rejected product analysis should be consistent with determination of root cause, corrective action and monitoring effectiveness of implementation.

8.5.3 Preventive action **4.14.1.1 4.14.1.3 4.14.3**

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

a) A documented procedure shall be established to define requirements for

~~c)~~b) determining potential nonconformities and their causes,

~~e)~~c) evaluating the need for action to prevent occurrence of nonconformities,

~~g)~~d) determining and implementing action needed,

~~i)~~e) records of results of action taken (see 4.2.4), and

~~k)~~f) reviewing preventive action taken.

8.5.3.1 Mistake-proofing for preventive action

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

Add here some annexes coming from ISO 9001:2000, TS 1st, or new ones