



L'AUDIT DU SYSTEME DE LA QUALITE'
 QUALITÄTSSYSTEMAUDIT

1 - MANAGEMENT RESPONSIBILITY

1.1 - QUALITY POLICY

The supplier's management shall define and document its policy and objectives for, and commitment to, quality. The supplier shall ensure that this policy is understood, implemented and maintained at all levels in the organisation.

1.2 - ORGANIZATION

1.2.1 Responsibility and authority

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

- a) initiate action to prevent the occurrence of product nonconformity;
- b) identify and record any product quality problems;
- c) initiate, recommend or provide solutions through designated channels;
- d) verify the implementation of the solutions;
- e) control further processing, delivery of installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.

The responsibility, authority, duty and the interrelation of all personnel who manage, perform and verify work affecting quality is to be laid down clearly in job descriptions. These ones have to be accepted by management and routed to the functions involved such as Sales, Product Engineering, Production Engineering, Quality, Production, Purchasing and Dispatch.

In this context the interrelations / interactions / cooperations of the functions involved should be laid down clearly in flowcharts identifying each step of activities and forms in use.

1.2.2 Verification resources and personnel

The supplier shall identify in-house verification requirements, provide adequate resources and assign trained personnel for verification activities (see 18).

Main changes compared to the last issue:

Verification activities shall include inspection, test and monitoring of the design, production, installation and servicing processes and/or products; design reviews and audits of the quality system, processes and/or product shall be carried out by personnel independent of those having direct responsibility for the work being performed.

1.2.3 Management representatives

The supplier shall appoint a management representative who, irrespective of other responsibilities, shall have defined authority and responsibility for ensuring that the requirements of this International Standard are implemented and maintained.

The supplier appoints a representative at management level (top management / management board / board of directors) the Q-Manager reports to directly. The management member represents the Q-authority at board level. The Q-Manager is responsible to the management as such.

1.3 - MANAGEMENT REVIEW

The quality system adopted to satisfy the requirements of this International Standard shall be reviewed at appropriate intervals by the supplier's management to ensure its continuing suitability and effectiveness. Records of such reviews shall be maintained (see 16).

Note - Management reviews normally include assessment of the results of internal quality audits, but are carried out by, or on behalf of, the supplier's management, viz. management personnel having direct responsibility for the system (see 17).

An audit system is to be installed whereby management introduces an audit plan, appoints an audit team and follows up on the reports as far as acceptance and follow-up on corrective actions is concerned if applicable. Further is to be pointed out that this responsibility remains with management and is its very task to maintain strict adherence.

2 - QUALITY SYSTEM

The supplier shall establish and maintain a documented quality system as a means of ensuring that product conforms to specified requirements.

This shall include:

- a) the preparation of documented quality system procedures and instructions in accordance with the requirements of this International Standard;
- b) the effective implementation of the documented quality system procedures and instructions.

Note - In meeting specified requirements, timely consideration needs to be given to the following activities:

- a) the preparation of quality plans and a quality manual in accordance with the specified requirements;
- b) the identification and acquisition of any controls, processes, inspection equipment, fixtures, total production resources and skills that may be needed to achieve the required quality;
- c) the updating, as necessary, of quality control, inspection and testing techniques, including the development of new instrumentation;
- d) 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;
- e) the clarification of standards of acceptability for all features and requirements, including those which contain a subjective element;
- f) the compatibility of the design, the production process, installation, inspection and test procedures and the applicable documentation;
- g) the identification and preparation of quality records (see 16).

A Quality Handbook (Manual) is to be introduced, identifying clearly all activities within the company referring to the product and its quality requirements.

The Q-Handbook has to be drawn up in line with the chapters of ISO 9001.

The following is meant by Quality plan:

For projects relating to new products, services or processes, management should prepare, as appropriate, written quality plans consistent with all other requirements of a company's quality management system.

Quality plan should define:

- a) the quality objectives to be attained;
- b) the specific allocation of responsibilities and authority during the different phases of the project;
- c) the specific procedures, methods and work instructions to be applied;
- d) suitable testing, inspection, examination and audit programmes at appropriate stages (e.g. design, development);
- e) a method for changes and modifications in quality plan as projects proceed;
- f) other measures necessary to meet objectives.

At least the wheel division of Euwa-Members should introduce an internal system (Quality plan) which allows that, upon receipt of the order for developing a wheel, a project plan - Q-plan - is designed, covering all activities around the product from: (a comprehensive check list is recommended)

- design review
- FMEA (design + process)
- feasibility study
- acceptance of all customer requirements and obtaining the mutual agreement of the parties involved
- identification of safety critical characteristics, if there are any.

- tool design
 - inspection plan, design and obtaining of specific inspection equipment if applicable
 - packing
 - dispatch and supply formalities
- to: production control by latest approved design status.

For the project as such, one project leader is to be appointed who co-ordinates the members' activities and who is responsible for timeous follow-up in order to meet the targets and schedules set and agreed upon with the customer.
(This note applies to 4.3 and 4.4 as well).

3 - CONTRACT REVIEW

The supplier shall establish and maintain procedures for contract review and for the co-ordination of these activities.

Each contract shall be reviewed by the supplier to ensure that:

- a) the requirements are adequately defined and documented;
- b) any requirements differing from those in the tender are resolved;
- c) the supplier has the capability to meet contractual requirements.

Records of such contract reviews shall be maintained (see 16).

Note - The contract review activities, interfaces and communication within the supplier's organisation should be co-ordinated with the purchaser's organisation, as appropriate.

Additionally, it has to be pointed out clearly that, in the stage of contract review, the customer's demands and the supplier's offer/tender should be brought to identity. Sometimes is experienced that e.g. tolerances are accepted which cannot be made, requirements are accepted to be adhered to but are frequently and permanently ignored.

The tender should not only be confirmation of the customer requirement, completed by a price, but should clearly stipulate where and in which point the supplier's offer differs from the request for quotation. At all stages, the wheel manufacturer should be aware of his liability in case anyone of the specified characteristics of a wheel is not maintained and documented.

The contract finally contains the terms agreed upon. All correspondence and notes are kept in one file for the lifetime of the wheel and a period after production stop, agreed upon by both contractors.

The records of contract review are kept by sales.

The Euwa-Members representative in negotiation with the customer should not be in the position to accept requirements as a dictate. Offensive negotiation in order to be not trapped in legal liabilities immediately is strongly recommended.

Irrespective of existing contracts unmentioned differences of the past should be eliminated by every new contract.

In order to cope with the demand of this point of ISO 9001 team-work in the Euwa-Member companies is to be stressed the answer.

4 - DESIGN CONTROL

General aspect under design control is to identify at all stages of development the status of documents like drawings, specifications, tool-design, work spec's etc.

4.1.1 General

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

4.1.2 Design and development planning

The supplier shall draw up plans that identify the responsibility for each design and development activity. The plans shall describe or reference these activities and shall be updated as design evolves.

4.2.1 Activity assignment

The design and verification activities shall be planned and assigned to qualified personnel equipped with adequate resources.

4.2.2 Organisational and technical interfaces

Organisational and technical interfaces between different groups shall be identified and the necessary information documented, transmitted and regularly reviewed.

4.3 - DESIGN INPUT

Design input requirements relating to the product 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 drawing up there requirements.

4.4 - DESIGN OUTPUT

Design output shall be documented and expressed in terms of requirements, calculations and analyses.

Design output shall:

- a) meet the design input requirements;
- b) contain or reference acceptance criteria;
- c) conform to appropriate regulatory requirements whether or not these have been stated in the input information;
- d) identify those characteristics of the design that are crucial to the safe and proper functioning of the product.

4.5 - DESIGN VERIFICATION

The supplier shall plan, establish, document and assign to competent personnel functions for verifying the design.

During verification shall establish that design output meets the design input requirement (see 4.4) by means of design control measures such as:

- a) holding and recording design reviews (see 16);
- b) undertaking qualification tests and demonstrations;
- c) carrying out alternative calculations;
- d) comparing the new design with a similar proven design, if available.

ISO 9001 item 4.4.5, requires design verification.

At first Euwa-Members own design: there should be an institution within the company to verify the design upon finalization by design department. At this stage, it is the designer's responsibility to obtain written confirmation by quality, production, engineering and other departments involved as far as functioning of the wheel is concerned.

At second design supplied by customer accepted to be governing: in this case as well design review applies. Procedure as before. For wheel supplies, components with safety critical characteristics to be documented, the responsibility for proper functioning always lies with the manufacturer. Therefore, it is his duty to analyse field problems if there are any and to modify design accordingly.

In both cases, modifications to the design should be accepted by the customer formally and in writing.

4.6 - DESIGN CHANGES

The supplier shall establish and maintain procedures for the identification, documentation and appropriate review and approval of all changes and modifications.

As additional remarks, not only first in first out of products of identical drawing level is concerned but all records, operational sheets, drawings, inspection instructions and any other documents referring to this product being changed are updated by the latest level at the very same controlled moment.

The production control and dispatch advises accordingly.

5 - DOCUMENT CONTROL**5.1 - DOCUMENT APPROVAL AND ISSUE**

The supplier shall establish and maintain procedures to control all documents and data that relate to the requirements of this International Standard. These documents shall be reviewed and approved for adequacy by authorised personnel prior to issue.

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) obsolete documents are promptly removed from all points of issue or use.

5.2 - DOCUMENT CHANGES / MODIFICATIONS

Changes to documents shall be reviewed and approved by the same functions / organisations that performed the original review and approval unless specifically designated otherwise.

The designated organisations 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.

A master list or equivalent document control procedure shall be established to identify the current revision of documents in order to preclude the use of non-applicable documents.

Documents shall be re-issued after a practical number of changes have been made.

6 - PURCHASING**6.1 - GENERAL**

The supplier shall ensure that purchased product conforms to specified requirements.

6.2 - ASSESSMENT OF SUB-CONTRACTORS

The supplier shall select sub-contractors on the basis of their ability to meet sub-contract requirements, including quality requirements. The supplier shall establish and maintain records of acceptable sub-contractors (see 4.16).

The selection of sub-contractors, and the type and extent of control exercised by the supplier, shall be dependent upon the type of product and, where appropriate, on records of sub-contractors' previously demonstrated capability and performance.

The supplier shall ensure that quality system controls are effective.

Euwa-Members keep lists of approved sub-contractors, whereby the assessment result, product quality performance and periodic audit results from the basis of such a list. Responsible is the purchasing office.

6.3 - PURCHASING DATA

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

- a) the type, class, style, grade or other precise identification;
- b) the title or other positive identification, and applicable issue 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 International Standard to be applied to the product.

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

6.4 - VERIFICATION OF PURCHASED PRODUCT

Where specified in the contract, the purchaser or his representative shall be afforded the right to verify at source or upon receipt that purchased product conforms to specified requirements. Verification by the purchaser shall not absolve the supplier of the responsibility to provide acceptable product nor shall it preclude subsequent rejection.

When the purchaser or his representative elects to carry out verification at the sub-contractor's plant, such verification shall not be used by the supplier as evidence of effective control of quality by the sub-contractor.

7 - PURCHASER SUPPLIED PRODUCT

The supplier shall establish and maintain procedures for verification, storage and maintenance of purchaser supplied product provided for in- corporation into the supplies. Any such product that is lost, damaged or is otherwise unsuitable for use shall be recorded and reported to the purchaser (see 16).

NOTE - Verification by the supplier does not absolve the purchaser of the responsibility to provide acceptable product.

8 - PRODUCT IDENTIFICATION AND TRACEABILITY

Where appropriate, the supplier shall establish and maintain procedures for identifying the product from applicable drawings, specifications or other documents, during all stages of production, delivery and installation.

Where, and to the extent that, traceability is a specified requirement, individual product or batches shall have a unique identification. This identification shall be recorded (see 16).

Wheels, components and its material with safety critical requirements, are to be considered for identification and traceability during all stages of processing and service. On the basis of the individual system of the Euwa-member it could be recommended that all stores during processing and dispatch are handled on the basis of first in - first out. Batches are to be kept together.

9 - PROCESS CONTROL

9.1 - GENERAL

The supplier shall identify and plan the production and, where applicable, installation 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 work instructions defining the manner of production and installation, where the absence of such instructions would adversely affect quality, use of suitable production and installation equipment, suitable working environment, compliance with reference standards / codes and quality plans;
- b) monitoring and control of suitable process and product characteristics during production and installation;
- c) the approval of processes and equipment, as appropriate;
- d) criteria for workmanship which shall be stipulated, to the greatest practicable extent, in written standards or by means of representative samples.

9.2 - SPECIAL PROCESSES

There are processes, the results of which 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. Accordingly, continuous monitoring and/or compliance with documented procedures is required to ensure that the specified requirements are met. These processes shall be qualified and shall also comply with the requirements of 9.1.

Records shall be maintained for qualified processes, equipment and personnel, as appropriate.

10 - INSPECTION AND TESTING**10.1 - RECEIVING INSPECTION AND TESTING**

10.1.1 - The supplier shall ensure that incoming product is not used or processed (except in the circumstances described in 10.1.2) until it has been inspected or otherwise verified as conforming to specified requirements. Verification shall be in accordance with the quality plan or documented procedures.

10.1.2 - Where incoming product is released for urgent production purposes, it shall be positively identified and recorded (see 16) in order to permit immediate recall and replacement in the event of non-conformance to specified requirements.

NOTE - In determining the amount and nature of receiving inspection, consideration should be given to the control exercised at source and documented evidence of quality conformance provided.

10.2 - IN-PROCESS INSPECTION AND TESTING

The supplier shall:

- a) inspect, test and identify product as required by the quality plan or documented procedures;
- b) establish product conformance to specified requirements by use of process monitoring and control methods;
- c) hold product until the required inspections and tests have been completed or necessary reports have been received and verified except when product is released under positive recall procedures (see 10.1). Release under positive recall procedures shall not preclude the activities outlined in 10.2 a);
- d) identify nonconforming product.

10.3 - FINAL INSPECTION AND TESTING

The quality plan 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 data meets specified requirements.

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

No product shall be despatched until all the activities specified in the quality plan or documented procedures have been satisfactorily completed and the associated data and documentation is available and authorised.

10.4 - INSPECTION AND TEST RECORD

The supplier shall establish and maintain records which give evidence that the product has passed inspection and/or test with defined acceptance criteria (see 16).

As an additional recommendation, the spc./s- or R-charts should be evaluated in order to establish dates for preventative maintenance of manufacturing equipment in case the standard deviation is steadily increasing over the period considered.

11 - INSPECTION, MEASURING AND TEST EQUIPMENT

The supplier shall control, calibrate and maintain inspection, measuring and test equipment, whether owned by the supplier, or loan, or provided by the purchaser, to demonstrate the conformance of product to the specified requirements. Equipment shall be used in a manner which ensures that measurement uncertainty is known and is consistent with the required measurement capability.

The supplier shall:

- a) identify the measurements to be made, the accuracy required and select the appropriate inspection, measuring and test equipment;
- b) identify, calibrate and adjust all inspection, measuring and test equipment and devices that can affect product quality at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to nationally recognised standards - where such standards exist, the basis used for calibration shall be documented;
- c) establish, document and maintain calibration procedures, including details of equipment type, identification number, location, frequency of checks, check method, acceptance criteria and the action to be taken when results are unsatisfactory;
- d) ensure that the inspection, measuring and test equipment is capable of the accuracy and precision necessary;
- e) identify inspection, measuring and test equipment with a suitable indicator or approved identification record to show the calibration status
- f) maintain calibration records for inspection, measuring and test equipment (see 16);
- g) assess and document the validity of previous inspection and test results when inspection, measuring and test equipment is found to be out of calibration;
- h) ensure that the environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out;

- i) ensure that the handling, preservation and storage of inspection, measuring and test equipment is such that the accuracy and fitness for use is maintained;
- j) safeguard inspection, measuring and test facilities, including both test hardware and test software, from adjustments which would invalidate the calibration setting.

Where test hardware (e.g. jigs, fixtures, templates, patterns) or test software is used as suitable forms of inspections, they shall be checked to prove that they are capable of verifying the acceptability of product prior to release for use during production and installation 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 16).

Measurement design data shall be made available, when required by the purchaser or his representative, for verification that it is functionally adequate.

As a further recommendation to be considered, the accuracy - inaccuracy of measuring equipment is actually reducing the workable tolerance of components. Basis for the reduced working tolerance is the result of capability studies on measuring equipment. All measuring instruments in the factory are to be covered by a calibration service, this applies for example for temperature gauges (clocks) in curing tunnels for surface treatment as well. Who is responsible and how is it done. The actual measuring/calibration data are to be entered into the records, stating acceptance alone is insufficient.

12 - INSPECTION AND TEST STATUS

This inspection and test status of product shall be identified by using markings, authorised stamps, tags, labels, routing cards, inspection records, test software, physical location or other suitable means, which indicate the conformance or non-conformance of product with regard to inspection and tests performed. The identification of inspection and test status shall be maintained as necessary, throughout production and installation of the product to ensure that only product that has passed the required inspections and tests is despatched, used or installed.

Records shall identify the inspection authority responsible for the release of conforming product (see 16).

For this point, the management of the matter and discipline is of highest importance. The marking or identification method should be clearly identified in writing and all personnel being instructed accordingly.

13 - CONTROL OF NON-CONFORMING PRODUCT

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

Here again, a system description has to be performed in writing, identifying clearly the responsibility for treatment of non-conforming material. All personnel concerned is to be instructed accordingly.

13.1 - NONCONFORMITY REVIEW AND DISPOSITION

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, or
- b) accepted with or without repair by concession, or
- c) re-graded for alternative applications, or
- d) rejected or scrapped.

Where required by the contract, the proposed use or repair of product (see 13.1 b) which does not conform to specified requirements shall be reported for concession to the purchaser or his representative.

The description of nonconformity that has been accepted, and of repairs, shall be recorded to denote the actual condition (see 16).

Repaired and retorted product shall be re-inspected in accordance with documented procedures.

14 - CORRECTIVE ACTION

The supplier shall establish, document and maintain procedures for:

- a) investigating the cause of nonconforming product and the corrective action needed to prevent recurrence;
- b) analysing all processes, work operations, concessions, quality records, service reports and customer complaints to detect and eliminate potential causes of nonconforming product;
- c) initiating preventive actions to deal with problems to a level corresponding to the risks encountered;

- d) applying controls to ensure that corrective actions are taken and that they are effective;
- e) implementing and recording changes in procedures resulting from corrective actions.

Stressed should be here the closed loop of information. The initiator of corrective action should eventually know that action has been taken and the corrected operation now works sufficiently. Over and above this, the explanations in ISO 9004 should be read and studied carefully.

15 - HANDLING, STORAGE, PACKAGING AND DELIVERY

15.1 - GENERAL

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

15.2 - HANDLING

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

15.3 - STORAGE

The supplier shall provide secure storage areas or stock rooms to prevent damage or deterioration of product, pending use of delivery.

Appropriate methods for authorising receipt and the dispatch to and from such areas shall be stipulated. In order to detect deterioration, the condition of product in stock shall be assessed at appropriate intervals.

15.4 - PACKAGING

The supplier shall control packing, preservation and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements and shall identify, preserve and segregate all product from the time of receipt until the supplier's responsibility ceases.

15.5 - DELIVERY

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.

Contents under this chapter, and it may be stressed here, should carefully be negotiated by the parties involved and the responsibilities and duties be clearly stipulated. Test runs on packaging and delivery should be performed.

16 - QUALITY RECORDS

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

Quality records shall be maintained to demonstrate achievement of the required quality and the effective operation of the quality system. Pertinent sub-contractor quality records shall be an element of these data.

All quality records shall be legible and identifiable to the product involved. Quality records shall be stored and maintained in such a way that they are readily retrievable in facilities that provide a suitable environment to minimise deterioration or damage 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 purchaser or his representative for an agreed period.

Retention period for quality records on wheels should be 10 years generally as from date of supply, not 10 years from the end of production of this wheel as such or from production date.

The situation is unclear by distribution through dealers keeping stock for various times. Under the last condition a supply date is uncertain.

Euwa should take this matter over and establish one governing procedure ruling this matter under consideration of legal requirements.

Retention period of drawings, process plans, dispatch notes and other documents falling under this category should be covered as well.

Repetition of a comment referring to characteristics to be documented may be allowed here. Such characteristics may not be recorded to be out of tolerance, with other words, under any circumstances these characteristics are to be produced in tolerance, if not, components to be reworked or scrapped. Supplies of components with above-mentioned condition is not acceptable.

17 - INTERNAL QUALITY AUDITS

The supplier shall carry out a comprehensive system of planned and documented quality audits to verify whether quality activities comply with planned arrangements and to determine the effectiveness of the quality system. Audits shall be scheduled on the basis of the status and importance of the activity.

The audits and follow-up actions shall be carried out in accordance with documented procedures.

The results of the audits shall be documented 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 by the audit (see 1.3).

18 - TRAINING

The supplier shall establish and maintain procedures for identifying the 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 16).

Appropriate job descriptions should contain requirements referring to minimum training/qualification needs for the job. After certain periods training should be repeated. All activities referring to training should be laid down in training plans, its organisation, update and progress is organised by personnel dept. Particularly stipulated here is the need for training not only for Q- personnel but for all personnel working affecting quality.

19 - SERVICING

When servicing is specified in the contract, the supplier shall establish and maintain procedures for performing and verifying that servicing meets the specified requirements. Servicing does not apply to Euwa-members.

20 - STATISTICAL TECHNIQUES

Where appropriate, the supplier shall establish procedures for verifying the acceptability of process capability and product characteristics.

Although the content of this paragraph is generally acceptable, it is and remains the Euwa-members decision

- if
- how and
- which

statistical methods are applied and how product characteristics and process parameters are to be included in this consideration.