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## VdS-Leaflet

# Requirements for the performance of a main assessment according to DIN EN ISO 9001

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# 1 General requirements

The following explains which requirements must be fulfilled by the applicant before performing a main assessment. This list of items does not claim to be complete but lists the weak points which according to experience appear rather often.

To the requirements for a smooth audit process belongs the following:

- Presentation of a defect free quality management documentation (QM-documentation), consisting of a quality manual and corresponding procedures
- Receipt of the QM-documentation to a minimum of six weeks prior to the scheduled audit

Additional information on the above can be found in the ISO 9000 “Fundamentals and vocabulary” and in the ISO 9004 “Managing for the sustained success of an organization – A quality management approach”.

# 2 QM-documentation requirements

The QM-system of the company must be documented by a QM-manual. The manual must to a minimum contain the following:

- Scope of the QM-system (identification and description of the companies main/core processes),
- any exclusions from the requirements of the standard (possible only with regard to chapter 7 of the standard) and their justification,
- a description of the interaction of the QM-system processes and
- documented procedures of the QM-system or cross-references to them.

DIN EN ISO 9001 requires documented procedures for

- Document control (Chapter 4.2.3),
- Control of records (Chapter 4.2.4),
- Internal audits (Chapter 8.2.2),
- Control of non-conforming product (Chapter 8.3),
- Corrective action (Chapter 8.5.2) and
- Preventive action (Chapter 8.5.3).

Hence, the quality policy and quality objectives must be documented. It is also a requirement of the standard in various positions, that adequate records must be established. Advice about these required records will be given in the following paragraphs. Only by adequate records it will become evident that all requirements of the standard are fulfilled. As a result to this, the requirements of the standard with regard to quality records must be considered to be a minimum demand.

Due to the fact that documented procedures / processes will be verified by practical samples during the main assessment, every process must have been implemented in practice at least one time in the past. Corresponding samples will be witnessed on site and evaluated concerning their conformity with departmental procedures.
Documents and records can be made up in every appropriate form (paper, computer data). Records must be clearly identified. If records are filed on a computer system only, appropriate procedures for data backup must be considered. Retention times must be adequately fixed considering any legal and/or contractual demands.

# 3 Requirements in detail

DIN EN ISO 9001 forms a process oriented structure and emphasizes the central definitions “Customer Satisfaction” and “Continuous Improvement”.

In the following, some paragraphs of the DIN EN ISO 9001, which have been objected with regard to their fulfilment, will be commented:

**Chapter 5 – Management responsibility**

- Customer satisfaction as a central means of the new revision of the standard must be recognizable in the company as well as in its QM-documentation.
- Departmental quality objectives must not only be established but also checked upon their realization / current state.
- Responsibilities and authorities must be fixed throughout the whole organisation.
- Appropriate means for internal communication must be provided (e.g. public meetings/minutes, employee suggestion scheme, computer network, etc.).
- General ideas for input and results of the management review report are outlined in the standard. There must be at least one complete QM-system review report prepared by the management of the applicant.

**Chapter 6 – Resource management**

- Necessary resources with regard to training, education, personal skills and experience must be determined and provided. Hence there is the requirement concerning the evaluation of the effectiveness of performed training measures. There must be actual records about personal skills, experiences and training activities.
- Adequate infrastructure with regard to buildings, working places, process equipment and communication must be determined and provided.

- The work environment must be appropriate in order to fulfil any relevant product requirements.

**Chapter 7 – Product realization**

Requirements of this chapter mainly affect

- the customer related process to determine customer requirements, including tenders and contractual relations as well as customer communication. Offers, contracts and contract amendments must be prepared in a way which clearly determines all product requirements and –specifications. The evaluation, if all customer requirements will be fulfilled by the product, must be subject to documentation including verbal orders or amendments.

- the design of a product or a service. Design activities must be performed under scheduled, planned and controlled conditions. The design process must be subdivided into single design phases, starting with the design input, leading to a final product including all phases of design verification and –validation and all possible design changes. All these phases must be subject to documentation.

- purchasing activities. All purchased products and services must be clearly specified. Suppliers must be adequately evaluated. At least there must be an initial evaluation, which may be based upon the applicants experience or on a supplier self-evaluation. Incoming goods must be adequately inspected, to a minimum by an identification inspection.

- production or service provision with its subparagraphs

  - control of production or service provision.

  - process validation, if no appropriate measuring activities can be performed.

  - identification and traceability. If traceability is a (e.g. customer-) requirement, it must be subject to documentation

  - customer property, which may also be of mental nature. Cases of lost or damaged customer property must be subject to documentation.

  - product preservation including handling, storage, packaging, conservation and dispatch.

  - control of measuring and test equipment, which must be registered and marked in order to identify the calibration status. Measuring and test equipment must be calibrated at fixed intervals (preferably following the measuring and test equipment manufacturer's recommendations). Calibration results must be documented. The documentation must, among other things, give the following information: clear equipment identification, used reference standard and its traceability to national or international standards, calibration procedure and an evaluation of the calibration results. If equipment is found to be defective, the influence of this defect on formerly performed measures must be determined; possible corrective action on this must be implemented. Calibration software must be initially evaluated and released. This initial release can be performed by adequate incoming goods inspection (e.g. by sample testing and/or by test results of a pre-test).

**Chapter 8 – Measuring, analysis and improvement**

- Customer satisfaction
  Information on this item must be gathered and evaluated.

- Internal audits
  During internal audits it must be checked, if all determined and described processes are obeyed and meet the desired objectives. A documented procedure must describe all necessary audit documentation. A full internal audit must be performed prior to the main assessment. Corrective action on possible non-compliances must be specified, but not finalised at the time of the main assessment.

- Control and measuring of processes
  All processes within the QM-system must be regularly verified. This may happen during the internal audits.

- Control and measuring of product
  Every determined test activity for products and services must be performed. Quantitative attributes must be checked considering their specified acceptable tolerance spans. Records must clearly identify responsible test personnel.

- Control of nonconforming product
  It must be ensured, that nonconforming product will not come to delivery inadvertently. In the case that problems have occurred, traceable corrective action on every case must be subject to documentation.

- Data analysis
  Appropriate data must be evaluated and analysed in order to check and improve the suitability and effectiveness of the QM-system.

- Improvement
  Central element of the standard is the continuous improvement of the QM-system's effectiveness by using measurable quality objectives, internal audits, data analysis and a management review procedure. The consequent application of corrective and preventive action are rounding off this element.