VDA

Quality Management in the Automobile Industry

1

Quality Evidence

Guidelines for the Documentation and Archiving of Quality Requirements and Quality Records

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2nd completely revised edition 1998/1

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Verband der Automobilindustrie e.V. (VDA)

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Preface

In view of the permanently increasing quality requirements, quality improvement of products manufactured by the automobile industry, vehicles as well as their components, but also services will gain more and more importance. The Verband der Automobilindustrie (VDA) has initiated the establishment of a working group, in order to create one of many prerequisites, not only to maintain the quality level that has actually been reached, but to be able to increase it even further - and this in an economically reasonable scope -; this group should re-consider the subject of ”duty of documentation” from today’s view and define the results thereof in a revised 2nd edition of Volume 1 of the VDA series of documents "Quality Management in the Automobile Industry". The duty of filing documents that today exists only partially, has been designated by the short term "duty of documentation" and has become the determining element in Volume 1 ”Parts to be documented by automobile manufacturers and their suppliers” which was established in 1973. In addition, there has been the intent to increase the safety of certain parts, the so-called safety parts, by obtaining a documentation of e.g. test results through the use of the D marking. The 2nd revised edition however deals mainly with the true reason for the filing of documents, the demonstration of proof.

It can be seen today, that no quality improvement can be reached by filing quality documents and specifically with the related archiving procedure. The quality standard that was achieved is documented only. Nevertheless, a company may want to or will have to demonstrate proof for various reasons (audit, recall, product liability, requirements from public authorities), that its quality management system is functioning and that only those products are manufactured which comply with all requirements. Documents play an important role with regard to this procedure of demonstrating proof. Therefore, this subject is treated with priority in the present paper.

This paper should be understood as guideline, i.e. each entrepreneur must define himself:

- how he will comply with the requirements of his customers,
- how he will assure quality,
- how he will describe it,
- how he will deal with requirements of public authorities,
- how he will assure the efficiency of the measures planned by him, and
- to which extent he will protect himself against which problems.

This 2nd edition is addressed to management representatives, in order to provide them with information, why they must take care of the management of documents, as well as to planning representatives, to give them an overview on what must be considered, in order to have documents that are suited for the demonstration of proof under economical aspects.

We are grateful to the companies involved and to their representatives for having contributed to compile this volume. Contributions were made by the following companies:

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TRW Fahrwerksysteme GmbH & Co. KG
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We are also grateful to all those who have given us hints for the elaboration and for improvements.

The present 2nd, complete and revised edition was approved in 1997 by the ”Quality Management” committee of the VDA.

Frankfurt/Main, May 1997

VERBAND DER AUTOMOBILINDUSTRIE E. V. (VDA)

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1 Introduction

Today, the major competitive factors are deliberate customer orientation as well as quick implementation of all customer requests and customer expectations regarding marketable products and services together with a continuously reduced number of complaints.

By using a philosophy of comprehensive quality management the responsibility for the quality of products and services has been extended to all areas of the corporation, in order to achieve these goals. Everyone in Marketing, Engineering, Production Planning, Manufacturing, in Service etc. will contribute with his quality awareness and his work to maintaining and even further improving the corporate goal "high quality standard of products and services". Another corporate goal consists of course of manufacturing products and of providing services in an economical way too.

One prerequisite for achieving these goals is a comprehensive quality management system, by which all corporate processes have been defined and related responsibilities have been defined and clearly explained, by which the implementation has been supervised, introduced processes have been controlled, and measures of improvement have been introduced, if applicable.

Besides the requirements for the control and improvement of the processes, customers, legislation, and standards may require, among others, that proof of the quality requirements and the quality standard achieved is demonstrated at a certain point in time. One prerequisite for such a proof will be given by the definition and documentation of the quality requirements. Another prerequisite consists of the documentation of the compliance of these quality requirements in quality records. Both have in common, that all documentation regarding the demonstration of proof must be complete and unambiguous.

The capabilities and goals that are required by the processes will be described in documents during the planning phase, e.g. in the QM plan (see VDA Volume 4.3). A manufacturing process for example will be described in manufacturing plans, control plans, and inspection plans. Test results will show, if these specifications have been met.

In total, all documents represent material that is required by the management for the control of the corporation - independent of all legal, contractual or normative requirements.

In case of proofs prescribed by law and agreed upon by contract there is no alternative regarding the contents of the documentation and the archiving. Only the type and form of archiving may vary under consideration of the specifications. Examples are: Complete product documentation, inspection results of individual characteristics, condensed inspection results, results from audits, results from product reviews etc..

Besides, there is a series of opportunities for the so-called "voluntary" archiving. The scope of voluntary archiving should be planned carefully and kept within certain limits.

In addition, the quality status of the products achieved and the processes utilized for their manufacture must be observed also, when defining the procedure for example for the proof of the specified requirements and their compliance. It is therefore practical to develop and introduce procedures and courses of action which will allow a reduction of expenditure for the demonstration of proof, when increasing the quality status of products and services.

This may mean, for example, that an inspection of the product at the end of a process may not be required, but that it is sufficient if one can prove, that the process was under control and was capable at the time of the manufacture of the product.

The present Volume has been based on the idea, that for the above named reasons, today the application of quality methods is part of the state of the art, and that the availability of their documentation is necessary within a certain period of time. Among these quality methods are for example those summarized under the term of statistical process control (SPC), such as the keeping of quality control charts or collective non-conformity charts and also charts for process supervision and the compilation of master sample reports.

These tools for quality assurance in production will be supported by supplementary methods of preventive quality assurance. Among those you will find among others the Failure Mode and Effect Analysis (FMEA), the statistical planning of experiments (Design of Experiments, DOE), Quality Function Deployment (QFD) etc., just to name a few important tools.

If documents are referred to in this Volume, then those documents are meant which play a major role in quality management. But since quality is a characteristic that affects all parts of a corporation, the difference to be made between general documents and quality documents is not important.

2 Definition of Terms

The VDA series of documents is meant to be a supportive means, a tool and guideline. This must be understood by the partners with regard to the meaning of the terms used. Therefore, this paragraph describes several important terms for the introduction to this subject matter. Here, definitions from ackknowledged institutions such as DIN or DGQ willl be disregarded. They can be found e.g. in DIN EN ISO 8402, DIN 55 350, and DGQ Publication 11-4.

If one term has several meanings, then the meaning which has been printed in **bold** in the following explanations shall be used as standard in this Volume.

Demonstration of Proof

There are several reasons, why you want to prove, that the quality has been or can be reached as planned in accordance with the defined requirements. In general, documented quality requirements and the related inspection results (quality documents) are required, in order to demonstrate this proof. But this proof can also be shown by the demonstration or representation of the process that has been intended to be the one leading to quality, or by a marking on the product showing that the product has undergone defined tests successfully.

Also, not all requirements can be defined in a document - i.e. on paper or in an electronic way -, for example, characteristics that can technically not be completely described, which will then be defined by a master sample.

On the other hand, defined requirements cannot be tested 100 % (destructive testing!) and can therefore not be registered either. In this case the safety of the related manufacturing processes may be tested and registered.

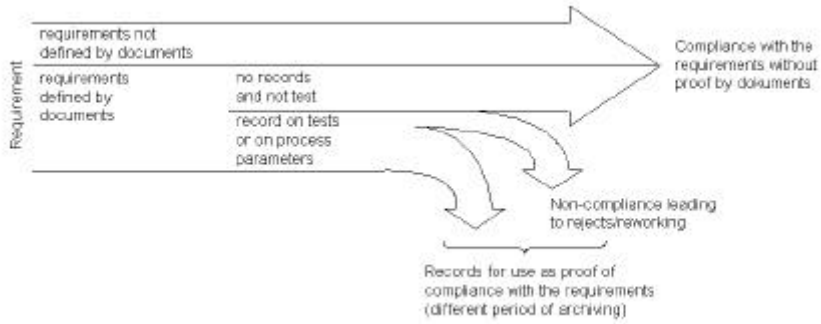


Figure 2-1: Demonstration of proof for compliance with the requirements

The demonstration of proof may become necessary for various conditions of interest:

- the corporate management wants to be sure, that the QM system is functioning
- someone responsible wants to know, how sure he can be, that the requirements of a product can be met
- a public authority may require proof as part of a public permission
- proof may be required to weaken an allegation (negligence, wrongful intent) raised by legislation or public authorities
- the customer (buyer of the product) may request that proof should be demonstrated (compliance with contract).

The proof itself may be as varying as it may be comprehensive. You may demonstrate proof pertaining to

- a product (e.g. product audit on the final product or inspection of the quality of one characteristic)
- a process (e.g. process audit)
- a system (e.g. auditing, certification).

(Quality-Related) Documents	
Quality Requirement Documents	**Quality Records**
Documented QM Procedures	**Important Control Records**
QM manual Documented procedures Manufacturing plans Inspection procedure description Directives Standards Project descriptions (in the sense of a documented working procedure)	Minutes of meetings QM system audit results QM system certificates
Product Specifications	**Important Product Records**
Drawing List of specifications Technical delivery requirements Purchase agreement Bills of material Inspection procedures	Inspection results Test reports Product audit results Warranty statistics Product certificates
Subject to ongoing changes	**Must not be changed**

Figure 2-2: Itemization of the types of quality-related documents

Therefore, the demonstration of proof is the activity, by which the attempt is made to prove at hand of a **documentation**, that a performance (product or service) rendered complies with the requirements. Major elements in this regard are **documents**.

Documents

As shown in Figure 2-2, there are two completely different types of documents. One type of documents largely describes requirements of processes and products, the second type represents the records of the results regarding activities and inspections, i.e. the records of the review of the compliance of these requirements. Both types are called ”document” in this paper.

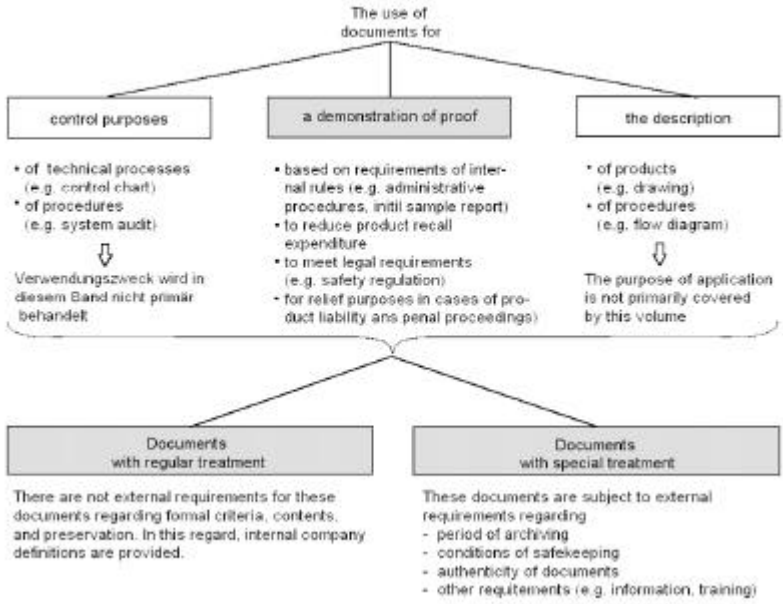


Figure 2-3: Interrelation between demonstration of proof and documents

On the other hand, documents are used for various purposes, e.g. to control an operation, for the demonstration of proof, or to describe conditions or products. In this regard it is not necessarily required to establish different documents. In many cases, the same documents may be used for several purposes. The interrelations are explained in Figure 2-3.

Documents that stand a legal review are designated here as **true documents,** all other common documents as **non-true documents**.

Documentation

In this relation, documentation is used as "compilation of documents" as well as in the sense of "descriptive evidence" (synonym for demonstration of proof). In various papers the terms "demonstration" or "disclosure" are also being used. It is likely, that any uniform use of the term cannot be assured.

To Document

This term should be used in the sense of "creating documents". This includes for example:

- compilation of product specification
- compilation of manufacturing plan
- recording of test results
- creating a delivery note
- creating a training certificate.

But to document will also be used in the sense of "demonstrating proof, that ...". In the more familiar language ”to document” is very often used for "preserving". This interpretation should not be used.

Documents with Special Archiving

Documents with special archiving (**DwSpA**) are documents defined by the corporation (see general Paragraph 6.1) and subject to a special archiving procedure (for the marking of DwSpA see general Paragraph 6.2).

Product

Besides the proper final product, representing a technical component, product also means the result of any activity, e.g. of planning, design, sales negotiations or training regarding the individual products: Manufacturing plan, drawing, purchase agreement, training certificate etc..

Period of Safekeeping

The period of safekeeping is the time span from the moment of creation of a document to the moment of its destruction. It includes the time of use and of keeping on archives of the document.

Period of Use

The period of use of a document is the time span during which the document is used for quality control purposes (see Figure 5-1 and 5-2). For example, an inspection plan will be used for quality control as long as the product is being manufactured and inspected according to an inspection procedure derived from this inspection plan. The period of use of the old invalid inspection plan will end upon a modification. The old invalid inspection plan will be kept on archives too.

Period of Archiving

The period of archiving is the time after the end of use of the document. This time span depends on the reason for the demonstration of proof, for which the documents are required. A more detailed explanation can be found in general Paragraph 5.3.

Duration, Term, and Time

The designations **duration**, **term, and time** are almost used as synonyms while relating to safekeeping, use, and archiving. In case of duration, the focus is more on the length of time, and in case of term, the focus is more on the end of the period of time.

3 Reasons for the Demonstration of Proof

3.1 Quality Control

The goal of a corporation is among others, to manufacture products in an economical way and to render services in accordance with the quality requirements. For conducting the related necessary quality control, documents will be required, showing the quality requirements and the degree of their compliance. This means that a great variety of documents must be established and be kept on archives accordingly for the manufacture of products and the rendering of services, as well as for the implementation of the processses required. These documents established in view of achieving the corporate goal represent a multitude of documents, when compared to those requested in laws and contracts.

Mainly, these documentations are a result from the requirements of DIN EN ISO 9000 and following already.

Here are some examples of reasons for establishing documents:

- Control of quality within the QM system / process control
  - Corrective measures
  - Management review
  - Progress development of the QM system
  - Limitation and traceablility of non-conformities and of their possible consequences on all levels and in all sectors including the suppliers.
- Proof of qualification for quality audits
- Transfer of the know-how gained to new processes and products.

3.2 Economical Considerations

Economical considerations which are exceeding the pure control of the operation may be a reason for documentation too, e.g.:

- in the event of a recall from the field, or to minimize the scope and thus the expenditure at the automobile manufacturer by limiting the non-conformity to the products actually involved as precisely as possible
- in cases of liability and warranty claims by proving the condition of the product quality actually delivered
- in view of obtaining a more favorable rate at the liability insurer
- in the event of a transfer of the know-how gained to new processes and products.

3.3 Laws, Contracts, Standards, Association Rules

A considerable number of laws, contracts, standards, and association rules include the definitions of requirements with regard to the type of quality of products and with regard to procedures during their manufacture, the compliance of which must be proven too, if applicable.

Laws include the description of requirements relating to products (vehicles), that are participating in motor vehicle traffic. These include among others definitions of the prerequisites for type approval and manufacture. The minimum rules for the safety of manufacture are described in these laws as general requirements, and the extent of demonstration of proof has not been defined. For these reasons, a risk evaluation of the corresponding overall process will always be required too, in order to define the scope of documentation.

To give assistance for decisions in this regard, some of the most important requirements that were applicable at the time of printing have been named and interpreted. The following is a summary overview.

These laws include for example:

- Road Traffic Homologation Law, Germany, StVZO § 30
- Law on Liability for Defective Products, ProdHaftG dated 01 January 1990
- General Noise Emission Directive, 70/157/EEC
- General Exhaust Emission Directive 70/220/EEC
- General Directive 70/156/EEC in the version 92/53/EEC, Par. 10 Annex X, Initial evaluation
- Federal Motor Vehicle Agency (”KBA”) ”Anforderungskatalog zur Begründung der Herstellereigenschaft” (manufacturers qualification requirements) dated August 1993
- US Safety Regulations, Federal Motor Vehicle Safety Standards (FMVSS)
- US Environmental Protection Regulation, (Title 40, Chapter 1) Environmental Protection Agency, Subchapter C - Air programs.
- National Traffic and Motor Vehicle Safety Act of 1966, Issue 1082, revised through 31 October 1988
- Australian Motor Vehicle Certification Board, Conformity of Production-Manual-Circular 0-13-1.

In addition, customers require in contracts the compliance with standards and association definitions on quality management also. In this case, they must not only be considered as recommendations, but as contractual requirements. The same applies to the observation of the scientific and technical state of the art also.

Related examples are:

- Standards on Quality Management according to DIN EN ISO 9000 and following
- Association Definitions Quality Management, such as VDA Volume 6.1, $EAQF_{94}$, FIEV, AVSQ, QS 9000
- Military Requirements on Quality Management AQAP 100 and following
- German Industry Association (BDI)/Government Standard Agreement, Annex X, Par. 1 of Article 10 of the Council Directive 92/53/EEC
- VDA Recommendations of 15 AUG 1995 ”Allgemeine Gechäftsbeinungen für den Bezug von Produktionsmaterial und Ersatzteilen, die für das Automobil bestimmt sind” (General business terms and conditions for the procurement of production material and spare parts intended for automobiles).

3.4 Product Liability, Penal Law, and Due Care

It may be practical or necessary also during the course of handling or in view of a rejection of product liability claims to be able to prove, that the procedure as anticipated/requested in the appropriate laws have been adhered to during the manufacture of the related product. The most important content of the corresponding laws is explained in the following, in order to be able to select the suitable documents.

3.4.1 Product Liability

The general rule is, that evidence must be shown, that all legal requirements imposed and those of due care have been met, e.g. that the scientific and technical state of the art has been met, or that all obligations of selection, supervision, and organization have been met.

Depending upon the case, e.g. in the event of a private or commercial damage, with or without compensation for pain and suffering or combinations thereof, different claim bases may be used against manufacturer and supplier by the plaintiff, parallel and as supportive element: Liability depending on wrongful doing (Liability in tort according to § 823, BGB - Civil Code) or liability independent of wrongful doing (Liability law for defective products, ”ProdHaftG” - Product Liability Law).

On liability it must further be distinguished between the aspects of private law and penal law. In the event of private liability claims, the focus will mostly be on the legal entity (company), whereas liability in penal law cases is always related to a natural person (individual person).

For more detailed relations, see schematic overviews in the Annex.

Liability Depending on Wrongful Doing (Liability in tort according to § 823-BGB - Civil Code)

> Every employee in the company must, according to his/her area of duty and responsibility, meet his/her obligations of due care. Based on the tortious general clause of § 823 Subpar. 1 BGB - Civil Law, the following applies:
>
> "... those, who illegally cause injury to the life, body, health, freedom, property or to any other right of others in an intentional or negligent way, are liable to those others for replacing the damage resulting thereof".
>
> This means, that everyone must behave in such a way, that there will be no illegal causes for any injury to any person or any objects of a third party within the area of his/her control. Everyone must take the required and sufficient measures within the scope of his/her possibilities and reasonableness, in order to avoid any hazards to those rights. In case of intentional or negligent infliction of this obligation, the injured party has the right for compensation of his/her damages.

The shifting of the burden of proof in product liability cases which is in general implemented by legislation represents a relief to the plaintiff with the consequence, that the defendent must prove his "innocence" (see decision of the BGH - Federal Supreme Court dated 26 NOV 1968 on the fowl pest).

Liability that is Independent of Wrongful Doing (Liability law for defective products, "ProdHaftG")

The shifting of the burden of proof has become the principle within EU product liability. Here, as opposed to the liability in tort, no fault is anticipated any more, and the plaintiff must deliver a prima facie evidence only, i.e. the relation between his damage and the non-conformity of the product. § 1, Subpar. 4 of the product liability law explains:

"... the manufacturer shall carry the burden of proof in those cases, where it is in dispute if the obligation for damage compensation has been excluded".

> This means, that the plaintiff carries the burden of prima facie evidence only with regard to the cause and its effect on the damage.

3.4.2 Penal Law

The penal law always applies, when personal injuries or deaths were caused due to negligence. The product responsibility by the penal law always means that the individual employee will have to answer personally for his own doings. Therefore, several persons may be responsible by penal law for one and the same damage. Product responsibility includes the liability for positive (=active) doing as well as for non-action (=default). The prosecution by penal law is based on the responsibility for the source of the hazard, that has been created by bringing the product into service.

The product responsibility by the penal law means in general the liability for damages caused by conduct on purpose and by negligence. Conduct on purpose may be given, when a manufacturer does not respond after having recognized sources of hazard. Negligence may be given in case of violation of an existing obligation to exercise due care and where a cause-and-effect condition exists between the violation of duty and the damage occurred, as well as in cases, where the damage could subjectively have been foreseen and avoided.

The measures for due care in case of a violation of duty have been determined by technical regulations, by the state of the art, and finally by the expectations of service of the product users. The inherent residual risk that must be considered in an individual case (so-called permissible risk) will also be determined by the expectations of service.

3.4.3 Responsibilities and Due Care

The manufacturer's duties and responsibilities for the corporation are based on the common laws, such as the product liability law, and by the state of the art of technology. The general responsibility of the corporate management, the responsibility of the managing directors of the corporate divisions, and the responsibility of the management representatives as well as the distribution of responsibilities between manufacturers and suppliers must be described and established on a general regulatory basis.

Principle of General Responsibility and General Competence

The principle of general responsibility and general competence is applicable to the Board or the Corporate Management respectively, independently of any explicit interdepartmental distribution. This responsibility includes all initial obligations of due care (obligations of selection, supervision, and organization).

Organizational Structure

In general, the corporation must be organized according to the state of the art of technology (see product liability law ”ProdHaftG”). The tasks and responsibilities must be clearly defined and described in an organizational structure.

The subject of liability of the vicarious agent has been described in § 831 BGB (Civil Law): Corresponding rights and obligations may be transferrable under certain circumstances within the scope of responsibility of substitution.

Personal Responsibility of Employees

The personal responsibility may be shown as a responsibility of conduct of those, having caused the non-conformity directly within the operation. Everyone involved in engineering, design, manufacturing and sales and marketing is responsible for the correct (=defect-free) implementation of his tasks.

General Obligations of Due Care

Jurisdiction is requesting from manufacturers, that they apply the necessary due care according to the state of the art of technology in engineering, design, manufacturing, sales and marketing, and in product review. Due care is requested to the extent that is reasonably required to avoid non-conformities that would lead to a damage during the just use of the product. "Just" in this regard means, that the foreseeable or even common misuse of a product must be included in the considerations also.

Negligence is given, when the necessary due care has been omitted in service operation, i.e. when the objective mandatory due care has not been observed.

Due Care Obligations of the Operation

Due to the interlinking of tasks in the corporation as an organizational unit, those responsibilities are also overlapping, which develop from interior and inter-company task sharing and the interdepartmental areas of responsibility, and interrelations resulting thereof. The so-called secondary obligations are deducted from this structure of responsibilities, in most cases meaning obligations with regard to clarification of subject matters, conducting requests, and giving instructions.

Many issues which appear as mere practical decisions under productivity aspects may have an objectively legal content too, when considered under pure technical and business management aspects. Therefore, decisions on subject matters and on organization which are suitable and reasonable under productivity aspects may be legally incorrect (”defective”). In the event of a personal injury caused thereof (or that has not been avoided ”in breach of duty”), this may result in a co-responsibility of the managment representatives based on penal law.

4 Documents for the Demonstration of Proof

4.1 Task of the Demonstration of Proof

The demonstration of proof has been intended for the presentation of definitions and results of a quality management system in a corporation in front of internal and external departments and individuals. Internal departments and individuals are for example those, who specify and further develop the quality management system, who control and supervise quality, or who deduct other measures thereof. External departments and individuals are those, who certify the QM systems, or customers, suppliers, homologation authorities, insurers, legislators, courts, etc..

Typically, documents are used for the presentation of definitions and results; definitions are described in quality requirement documents and results are described in quality records (see Figure 2-2). Therefore, they must include complete, unambiguous, distinct, and allocatable information about what should be proven.

4.2 Nature of Documents

The nature of the documents originates from the purpose, for which they have been intended (Figure 4-1). In general, distinction must be made between common documents (non-true documents) and those that stand a legal review (true documents).

A common (non-true) document includes at least:

- the date of creation or recording
- the modification status
- the individual(s) responsible for the content
- the name of the inspector or of the one determining the recorded result
- their signature(s)
- The allocation to the delivered product lots, projects, manufacturing lots, production periods etc..

A true document (standing legal review) must, in addition to those of the common document, meet at least all the following criteria:

- they must be original documents (no condensed ones established later) or microfilm reproductions of the original documents or electronic documents on a data carrier, and
- proof must be shown of who in the company had the knowledge of the document (e.g. distribution list), and
- proof must have beeen given of the precautionary measures that exclude any falsification and mixing of the documents during the entire administration procedure, and
- its statements must be unambiguous.

But in this regard, a true document must not meet the conditions of a document in the legal sense (i.e. executed and signed by hand writing).

4.3 Object of the Demonstration of Proof and Related Types of Documents

The documents may show as object of the demonstration of proof

- the **QM system**
- the **process quality** in the production and product manufacturing process as well as in all other processes
- the **product quality** of the final product and the quality of the results from e.g. engineering and planning work

as well as all other processes (Figure 4-1).

Figure 4-1: Object of the demonstration of proof and type of documents.

QM System as Object of the Demonstration of Proof:

Companies with an established QM system that meets the definitions of DIN EN ISO 9000 and following, VDA 6.1 or the like, do have an appropriate systematic procedure, if strict application is implemented. Based on the corporate objectives as well as on the organizational structures and procedures, the structural of functions and responsibilities of the entire process chain is described. The documentation system is systematically described by the QM Manual, the documented procedures, and the working and inspection procedures for the worker level. The interfaces between the different levels and the responsibilities must be established clearly and be traceable. The implementation may for example be documented in the results of QM system audits.

Process Quality as Object of the Demonstration of Proof:

Process quality may be proven by quality-related documents and records which demonstrate compliance of the specifications of the QM system. These are for example:

- Results from process and product audit
- Requirement, planning, and proof of employee qualification
- Inherent residual risk figures from analyses, e.g. product and process FMEA
- Proofs for the processing of corrective measures
- Release documents for process qualification.

For the proof of quality of the manufacturing process the following will additionally be required if applicable, e.g.:

- SPC control charts
- Proofs of process capability, e.g. c_{pk} values
- Failure rates, collective non-conformity charts
- Registrations of process parameters.

Product Quality as Object of the Demonstration of Proof:

Product quality here means the product resulting from any activity. Any product quality will be proven by documents, showing the compliance with the specifications. These are for example:

- Results from product audits
- Inspection results of any kind
- Software structural diagrams
- Delivery notes, ordering calls
- Results from meetings (minutes)
- Internal and external customer complaints
- Inherent residual risk figures from analyses, e.g. product and process FMEA
- Design review compared to standards, normalization specifications, and internal as well as external requirements.

The above-mentioned specifications, according to which inspections are conducted are of course considered to be documents that are necessary for the demonstration of proof. (see Figure 2-2).

4.4 Allocation of Reasons of Proof and Types of Documents

The allocation of the types of documents described in the general Paragraph 4.3 regarding the different reasons for the demonstration of proof described in Par. 2 results in the subsequent detailed determination matrix for types of documents (Figure 4-2).

Demonstration of Proof	QM System		Process Quality		Product Quality	
	true document	non-true document	true document	non-true document	true document	non-true document
Internal Requirements						
- Process control		X		X		X
- Management review		X		X		X
- Certification		X		X		X
- QM certificates		X		X		X
Economical Consideratios						
- Efficient control of operations				X		X
- Localization of defective batches			X		X	
in case of recall				X		X
- Relief in case of general warranty claims			X		X	
Legal Requirements						
- Proof of design conformity	X		X		X	
- Proof of product conformity			X		X	
Product Liability, Penal Law						
- Relief in CASE of liability claims	X		X		X	
- Relief in CASE of penal prosecution	X		X		X	

Figure 4-2: Determination matrix for types of documents

5 Archiving

Archiving means the systematic registration, ordering, keeping and administration of the documents.

The documents can be divided into two groups:

- Documents with regular archiving and
- **D**ocuments **w**ith **Sp**ecial **A**rchiving (**DwSpA**).

Documents with regular archiving are intended for the proof of requirements related to the QM system and for the proving of compliance of the product with the quality requirements within a certain period of time. This certain period of time will be deducted from the normal business operation.

DwSpA (i.e. documents having a longer archiving period compared to "regular" archiving) will be the result for example from legal definitions, contractual agreements or from inter-company specifications (for reasons for the demonstration of proof see Par. 3, and for the selection of suitable documents see general Par. 6.1).

5.1 Regular Archiving

In view of archiving, one must in general distinguish between original documents and documents created by electronic data storage. The latter must in many cases be designated as "original documents" also, e.g. when they exist in electronic files only.

In general, original documents are paper documents (e.g. forms filled out by hand, EDP printouts, printouts from measuring and test equipment). Here, he most simple way of archiving is the filing of originals. In addition, there is the possibility to keep the original data on microfilm or on an electronic storage medium.

Requirements Regarding Archives Locations

Archives locations should provide sufficient assurance by protecting against fire and/or water as well as against unauthorized access, and should prevent from document alteration by appropriate backup measures.

An external service provider may also be used for archiving.

EDP Operation and Its Specific Requirements

Additional criteria must be observed, when archiving electronically stored data. First, one should decide, which data must be available online and offline, depending on the volume of the data and the existing hardware. In a corporation having appropriate hardware, online archiving should be preferred, e.g. by optical disk drive. In this regard, those systems should possibly be applied which do not allow any subsequent alterations (e.g. WORM: write once, read many).

With regard to the type of storage, the manufacturers recommendations on the durability of storage media should be observed. One must take care of refreshing the stored data in time (see also general Par. 6.4).

Basically, the decision about the necessity of the online access should be made under economical aspects and under consideration of the frequency of access to the documents that are kept on archives.

Organization of Archiving

The procedures and responsibilities introduced for archiving in a company should be defined in a documented procedure. These documented procedures should at least include information about

- which documents shall be kept on archives
- who is in charge of the storage
- who will refresh the data if applicable and how this will be done
- where the archives will be kept
- who has access
- how proof will be shown of the efficiency of the archiving system (auditing).

The departments responsible in the corporation should be informed about which documents qualify for archiving, about who is responsible for the keeping of the documents and where they are kept. In this regard, the question of access authorization must also be clarified and considered, so that the individuals with autorization to read cannot alter the data that were stored on archives.

Instructions for data backup in EDP operation are given in general Paragraph 6.4.

The QM elements of DIN EN ISO 9001 4.5 "Control of Documents and Data" and 4.16 "Quality Records" must be observed together with element 4.8 ”Identification and Traceability".

The type of file has a considerable effect on the access time to the documents. But short search times and thus quick access will in general require increased expenditure for archiving. Therefore, the economical expenditure should be estimated by a cost/profit analysis. The major item in this regard are the search criteria (e.g. the probability, that a document on archives will be used only once), from which the type of marking, registration and storage will be deducted. For practical reasons, this structure should be kept in an archiving plan.

After expiration of the archiving period the stored documents may be destroyed. The frequency of such action depends on the size of the archives and on the space available. It must be considered, that the records may include corporate confidential data. It must therefore be assured by appropriate measures (e.g. paper shredder), that the destroyed documents and data have been protected against unauthorized access.

Economy

The space required for archiving may be considerably reduced by electronically created documents, microfilm procedures or by the transfer of original documents to electronic (magnetic/optical) storage systems.

5.2 Special Archiving

In addition to the statements given in general Paragraph 5.1 for the regular archiving, the longer archiving period and the safer storage conditions if applicable shall apply to documents with special archiving (DwSpA).

Proof must be shown (e.g. in a product liability case) for true documents (see general Paragraph 4.2), that they were not altered or exchanged during their entire archiving period, or that individual documents were not destroyed. An inter-company regulation must be used to control this by appropriate documented procedures including the entire archiving system and the regular proof of the efficiency of the system. In this regard, careful consideration must be given to the fact, that such alterations are avoided by the type of archiving organization.

5.3 Time of Use and of Archiving

During the lifetime of a document one must distinguish between the time of use and the time of archiving. The time of use is the time, during which the document in service is being used. Once the document is not required any more, i.e. after the end of use the document will be stored on archives. Now, the time of archiving begins (see Figure 5-1 and 5-2).

The archiving begins for example

- for a quality requirement document (specification document), after it was modified and as the use of the new version begins
- for a quality record, after it is not required any more in service operation.

During both periods the document will be preserved - in most cases in a different way -, and this is called the time of safekeeping. The time of safekeeping begins with the creation and ends with the destruction of the document.

It must absolutely be observed with regard to the time of archiving, that this time does in most cases not begin with the creation of a document, but with its expiration e.g. by modification of the quality requirement document or by the termination of its use.

Any quality requirement document that has expired should be marked accordingly.

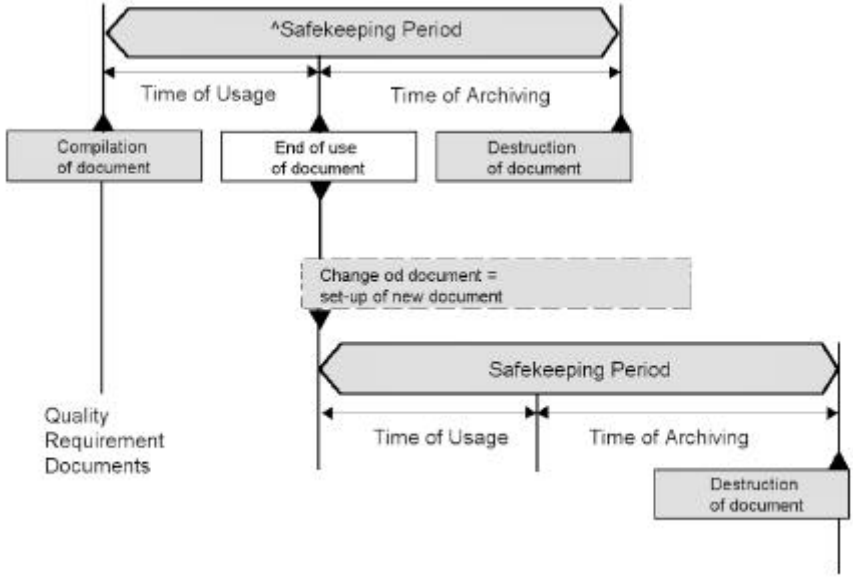


Figure 5-1: Safekeeping period of quality requirement documents

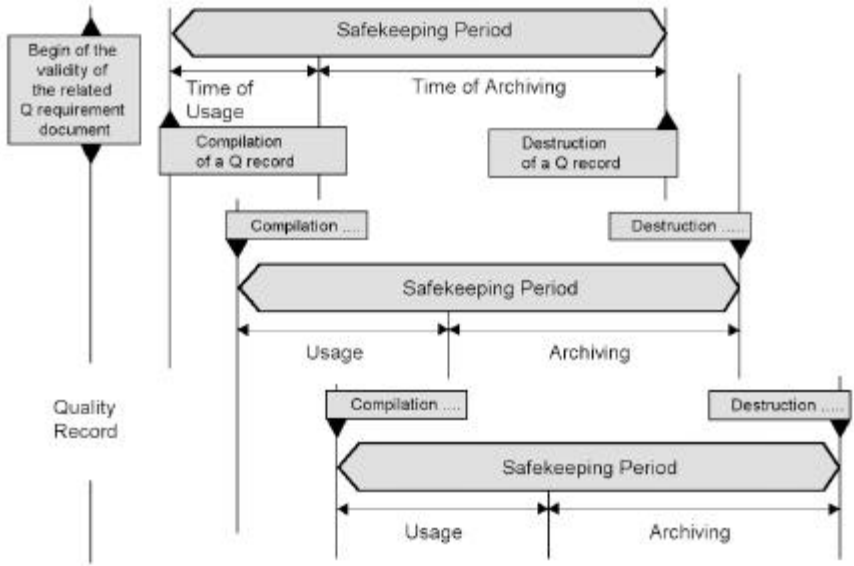


Figure 5-2: Safekeeping period of quality records

	Type of document	Time of archiving
Quality requirement document	Documents from the engineering phase and quality requirements from the production phase of the object of delivery (e.g. documented QM procedures, product specifications).	Begins with the delivery of the last product, which has been described in these documents, or after completion of the modification of a document, e.g. due to change of engineering status
Quality record	Records from the production phase of the object of delivery	Begins with the delivery of the product, to which the recordings regarding the product and the related process belong
	Records from the production phase of spare parts upon expiration of series production	Begins after termination of the production of the spare part

Figure 5-3: Begin of the time of archiving

A difference in the definition of the time of archiving between products of the actual series production and spare parts, even after expiration of the series production exists insofar only, that the time for storage of spare parts between their manufacture and delivery must be added to the time of archiving (see Figures 5-2 and 5-3).

There are no generally applicable guidelines or regulations for the time of archiving of documents.

When determining the time of archiving of documents from "normal business operation", one will use the internal requirements as guidelines, and the necessity for demonstrating an efficient QM system. Normally, shosrter times of archiving are sufficient for such documents, such as approximately 2 to 3 years. This period of time is sufficient, e.g. to prove the efficiency of the QM system.

Customer requirements too must often be considered for the time of archiving of documents. Therefore, quality agreements for example can be determined on a common basis with regard to which documents should be preserved on archives for how long.

For DwSpA a time of archiving of at least 15 years is being recommended for the following reasons:

- The average vehicle lifetime has been extended over the last years. It must be assumed, that after 15 years only, the majority of the vehicles will be withdrawn from service in traffic.
- As a result from the product liability law, the time of archiving is at least 10 years (statute of limitations). 3 years must be added for the period for objection of the plaintiff upon occurrence of the damage.

A specific aspect must be observed with ”wear-out parts” (e.g. brake linings and tires), which have a shorter lifecycle than the vehicle. It does not make much sense for these parts, which will be at least exchanged once during the lifetime of the vehicle, to define a time of archiving for the related documents that has the same length of time as the documetns for the vehicle. But this way of consideration cannot be applicable to the engineering documents of the wear-out parts.

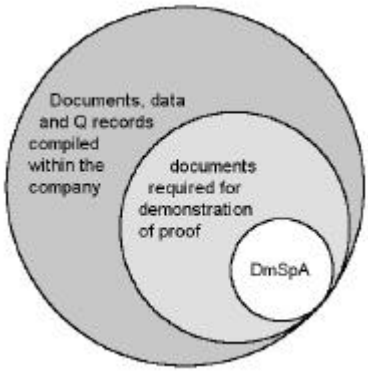
It may furthermore be practical to review, if a standardization to 15 years would be reasonable on the grounds of rationalization and to avoid problems with marking (mixing up) in view of a requested time of archiving between 2 and 15 years.

6 Practical Instructions for Implementation

6.1 Selection of Documents with Special Archiving (DwSpA)

6.1.1 General

Not all reasons for a demonstration of proof will require the definition of a ”special” archiving, this means a preservation that exceeds the regular, typical period of safekeeping in a business operation. Therefore, a selection must be made, and a marking of those documents may be required if applicable, which have been selected for a special archiving (see Fig. 6-1).



A corresponding selection and the separate treatment of DwSpA can be avoided, when - in case of the presence of appropriate prerequisites - the decision will be made, to generally treat all documents as DwSpA and keep them on archives in accordance with the longest time required. The modern technical methods of electronic data recording and storage allow more and more that this consideration will be realistic, at least for the compo-nents of a complete system.

Figure 6-1: Volume of documents

6.1.2 Selection of Documents

It can basically be assumed, that there are two types of DwSpA:

- legally prescribed ones and/or those agreed upon by contract
- those, defined by the corporation in their own interest ("voluntarily").

Any discussion about the documentation and archiving of the legally prescribed characteristics or those agreed upon by contract is unnecessary. These characteristics have been defined and cannot be discussed within the scope of this paper. They may be defined in the manufacturer's data sheet of specifications for the vehicle if applicable, and the suppliers may be informed about the corresponding specifications for their individual product/system.

This may be different with the DwSpA, which are being defined by the individual company based on their own interest. Therefore, in this paragraph the procedure for the selection of such documents only should be treated.

Here it is practical to undertake economical considerations about what will be the advantage, a company may have from special archiving. In most cases of these considerations the idea of being afraid of any tortious liability or product liability, or the argument of a less costly recall action play quite a role. For both cases a DwSpA may be helpful. But the cases that one may be afraid of should not occur in a company with a really functioning QM system. Recall actions and product liability cases can be avoided by preventive measures, sometimes by reactive quality measures too, and not by a functioning archiving system. It is extremely diffcult to select those parts or characteristics for a special archiving, on which nonconformities that may occur eventually will lead to such problems. Therefore, only the overall corporate strategy on how to deal with product design, process control, traceablility etc. can be of decisive importance. Therefore, we emphasize this practical recommendation:

The examples named in this brochure should in no case be used, in order to have them hastily applied in suitable cases. They represent hints only in view of the determination on how to possibly proceed in a special case that applies to the related company only.

To minimize the expenditure of archiving as much as possible when determining DwSpA, a careful risk analysis will be required in the product and process development phase, according to which the measures and characteristics that must specifically be documented will be identified. This includes for example those characteristics that have, after individual risk assessment, a considerable influence on vehicle safety or on the compliance with legal specifications (e.g. emission limits). According to the general understanding, the following subassemblies and components will among others have to be included in this regard,

- the brake system
- the steering system and wheel suspension
- the fuel supply and mixture formation system
- the engine management system
- the exhaust control system
- the noise emission system
- the illumination system,

because a functional failure of one component of these systems will represent a very high risk potential to the vehicle occupants or to the environment respectively.

But those subassemblies and systems should be included in the analyses also, on which functional non-conformities are of considerable importance to the driver ”only” (e.g. immobilization), because unexpected functional interruptions under certain realistic driving conditions may indeed be dangerous to the driver and may be the cause for a recall action.

Documents for the QM System

Besides the special archiving of proofs of product and process quality, it may also be required in some cases to be able to demonstrate even after a long period of time, how the procedures were organized and who at the time was responsible for them. For a demonstration of proof for example according to general Paragraph 3.3 and 3.4 mainly the documents relating to the structure of responsibility and certain documented procedures may apply, e.g. those intended to demonstrate, which quality tools had to be applied at which time and by whom.

Documents of the Product Development Phase

By using documents demonstrating the risk analysis of the product, e.g. system FMEA for product and process (see VDA 4.2) it will be possible to show proof, that a complete analysis of all product characteristics, specifically of those with very high non-conformity importance has been demonstrated, and that all risk-related conditions have been eliminated. The related test reports and alternative test methods (vehicle tests, finite-element studies, bench tests, prototype tests, fleet tests etc.) may prove, that the occurrence of any functional failure was practically not to be expected (where bench tests using a limited number of test specimen as proof are in general not sufficient).

To avoid inherent residual risks that would require the definition of DwSpA, all risks should be minimized carefully during the design and planning phase, and it should be checked, if the design as selected can be manufactured with the anticipated manufacturing methods while meeting process capability. requirements

Another reason for special archiving is in certain cases based on the necessity to demonstrate proof of the product-related quality requirements and of the processes used for testing and manufacturing. For this purpose, specific product-related quality requirement documents (specification documents) may be used, from the definition of the engineering concept to the specifications for the Service. If this is required, documents from this category may be used for the demonstration of proof, e.g. for

- Engineering projects (specification data sheet)
- Specifications for product design (drawings)
- Production and inspection procedures (QM plan, manufacturing and inspection plans, process data)
- Limit values for quality inspections.

Documents of the Process Development Phase

As in the product development phase, demonstration of proof is also possible in the process development phase by using those documents demonstrating the risk analysis of the processes (e.g. process system FMEA), that a complete analysis of all process-related risks, specifically of those having a very high non-conformity importance, has been conducted, specifically of those having a high non-conformity importance, and that all conditions that include any risks have been eliminated. It can de shown at hand of the corresponding process development reports (e.g. the correlation process/product characteristic, test results with statistical test

plans), that the occurrence of a product failure due to process non-conformities has practically been excluded. In such cases, the specification of process and product quality records as DwSpA may not be required for example.

Documents in Production

In manufacturing it may become necessary to demonstrate proof of those procedures and processes that were used for the manufacture of the product at a later point in time. The corresponding documents will then have to be specified as DwSpA. But more important are those records that document an actual condition at a certain point in time. These records will be established once and will not be modified any more thereafter.

On one hand, records may be used to demonstrate proof of the results from activities, such as

- system audits (to prove the functioning of the QM system)
- supervision of inspection equipment
- training measures,

on the other hand to demonstrate proof of the qualification (degree of compliance with the quality requirement) of a limited volume of products, such as

- results from testing
- release records
- process data registration
- process control charts
- inspection results
- results from product audits
- initiated and completed corrective measures.

Such records are specifically suited in those cases, where proof must be demonstrated, that the products delivered have met the specified quality requirements. In this case, it must absolutely be assured, that the documents can be allocated to the product volumes, to which they apply (see Par. 6.2.2).

But it should be critically reviewed in each case if it is necessary to treat the measuring values of all manufactured products with special archiving. Often, the demonstration of the product quality must be conducted by proof of process self-control too (e.g. by process control charts). On the other hand, it is often not sufficient or not necessary at all to demonstrate proof

of functional quality on delivery, but proof of other quality characteristics may be required (e.g. with regard to dependability).

To minimize the expenditure, a condensed statistical review and the application of control charts may be considered too (not applicable to 100% inspections with selective procedure) instead of documenting each product individually. Or, it may be sufficient to prove, instead of a documentation of all OK results, that the inspection system and its supervision (e.g. by random sample testing and/or by audits) are mandatorily assuring, that the products have run through a precisely defined and documented inspection procedure, while adhering to the limit values (e.g. automatic application of a permanent marking onto the product in case of OK results). In contrast, it will not be sufficient, to document the deviations only.

6.1.3 Economical Considerations

The most efficient and cost-saving method as well as the minimum expenditure possible should be used in any kind of documentation. But in this regard, limits are given for example by specifications from legislation or customers. But the basic rule is, that the expenditure for specific archiving can be influenced considerably by the careful selection of DwSpA. Also, it should be reviewed in regular intervals if the definition is still justified.

The following includes other instructions on this subject matter, without being complete:

- In the entire chain of production from the sub-supplier to the manufacturer the documentation should be coordinated with regard to minimum expenditure and in view of avoiding any duplicate documentation (each required characteristic should be documented only once).

- For specific archiving, no specific documents should be created, but already existing material should be used.

- If the definition of the DwSpA is within the product manufacturer's freedom of decisionmaking (no requirement from laws or from customers), then additional considerations are permissible. In this regard, two extreme positions may be possible:

    1. Besides the legally prescribed archiving, no additional archiving will be conducted besides the legally prescribed special archiving. Thus, there will be no extra costs for archiving. This procedure may be acceptable, depending upon the effects of possible functional non-conformities on the delivered products.
    2. "Everything" will be treated by special archiving. Despite the maximum costs in this case, assurance has not been given, that the characteristic or the part having caused the damage was in compliance with the specifications at the time of manufacture in a particular case.

The decision on how to proceed must be made by each company on its own under the consideration of the risk (see also Par. 6.5.2). Here are some more hints in this regard:

- By applying preventive QM measures(e.g. sturdy design, controlled and capable processes) the probability of a case of interruption can be minimized to such an extent, that the risk of a non-existing documentation may become acceptable. This can be supported by the use of preventive QM methods, e.g. by the FMEA (see VDA 4.2). It must be observed in this regard, that for example early failures during testing are considered as non-conformity, and that appropriate response is being undertaken.

- Special consideration should be given to the documentation of modifications, since they represent a special risk potential.

    - The customer may change the product or use it differently, without informing about such changes (this means for example interface description as DwSpA).

    - process changes may at the beginning not be recognized as being relevant, but will lead to problems later. This means for example, that equipment logs must always be kept with extreme precision, and be treated as DwSpA, in order to allow localizations at a later point in time.
    - the quality delivered parts may vary considerably, and deviations may be recognized too late, due to the skip lot method for example.

- If in the course of deliveries proof of compliance with specifications has been demonstrated by quality assurance agreements only, then carefully judgement is required on who is liable in the event of a damage.

- The completeness and truth of content of all records that have been compiled should be reviewed again and again for plausibility. Audits may be helpful in this regard.

- For special archiving, not as many characteristics as possible, but as few as necessary should be selected.

- The extent of the entrepreneur's acceptable risk should be calculated, depending upon the probability of occurence, the type or damage and ist amount. Examples for the consequences of missing or insufficient documentation are:

  - the scope of recall actions cannot be limited any more
  - no relief is possible in case of formal proceedings (e.g. in court)
  - increased insurance rates
  - no insurance possible

6.2 Marking of Documents and Equipment

6.2.1 Marking of DwSpA

All documents and records should always be marked with a date and show the issuing/recording party, and the modification status too if applicable. The allocation of any record to certain manufacturing periods, batches, deliveries etc., or to the scope of application of the documents should be possible (traceability).

There are no standardized specifications for the marking of documents that are subject to special archiving, and/or of the quality characteristics or activities to be documented, that were indicated on the documents. But it has been strongly recommended to the companies/users, to define uniform procedures (in-house standards) and to apply them throughout the process. Customer marking requirements relating to the archiving of documents should be included in this in-house standard as much as possible.

The following includes some proven types of marking as examples:

Individual Marking of Documents

The definition of a certain space on the document has been recommended in case documents and records will be marked. In case of preprinted forms or standard layouts, a certain space should be provided for this purpose. This space will then be filled out with the corresponding marking or it may remain empty.

In order to assure its recognizability, a minimum size, larger than the surrounding text, should be defined for the marking Also, the copying capability of the document should be considered, any exclusive color marking for example is not suitable.

In case of new definitions or modifications the letter "**A**" like for special **A**rchiving should be used for such markings as well as the use of one or several of the symbols indicated below.

The marking with the letter "D" as often used so far should support the awareness to demonstrate, that this represents a different type of "documentation" than understood by the term "duty of documentation" so far (see Preface and Introduction). The "D parts" as defined already according to VDA Volume Band 1, 1st edition, may be used as "D parts" in the future. But it has been recommended, to introduce the procedure described in this brochure at least with the new products, and to review the old "D parts" and conduct the changeover if applicable.

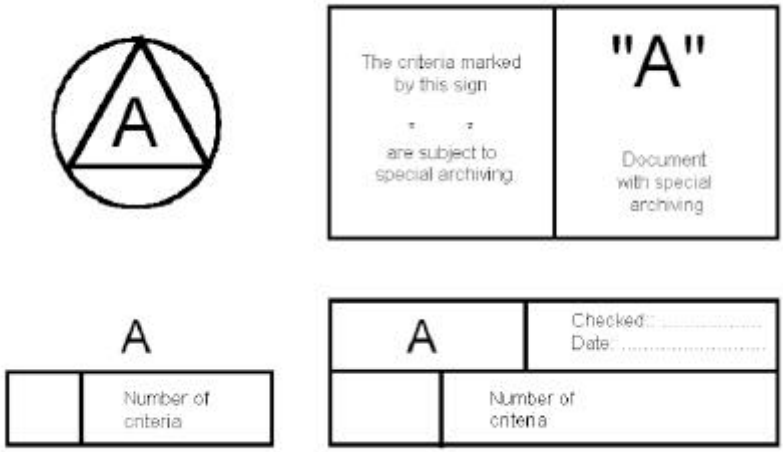


Figure 6-2: Examples for markings

Marking of Characteristics

As described on the documents marked above, several manufacturing steps, activities, inspections, quality characteristics etc. have been listed, the execution, results and data of which must not all be kept on special archives (e.g. on bills of materials, drawings, documented procedures, inspection procedures etc.). Therefore, those quality and process characteristics, procedures etc., intended for registration as DwSpA should have a specific marking. In this regard, the numbering of the characteristics with special archiving by running order on the document is a practical solution.

The following symbols are recommended for such markings:

Characteristic

A_x Characteristic (x =running numbering order)

(A) Characteristic

_____

Characteristic

Such a structure of a marked document and of the marked characteristics or reference documents contained therein may also be necessary in several steps. But basically, all documents marked that way should have a special archiving.

Archiving Plan for DwSpA

Also, the compilation of an ”archiving plan” for a product has been recommended as an alternative or as supplement to the marking of documents, i.e., a list containing all characteristics, process parameters, procedures, paperwork etc. that are DwSpA (e.g. quality requirement documents) or that should become a DwSpA (e.g. quality records). It is practical for this plan to include the definition of archiving responsibility, filing location and medium. This archiving plan should be part of the bill of material of the product.

The QM plan is also specifically suited for this definition.

Decision Criteria for the Type of Marking

The advantages and disadvantages of the individual marking or of the documentation plan have been compiled as an example in Figure 6-3 below. As an optimum, both procedures may be used in practice.

Documentation Plan		**Individual Marking**	
Individual document cannot be identified as DwSpA	-	Individual document can imme- diately be identified as DwSpA	+
Schematic overview of all DwSpA for a product	+		
Facilitates planning as a whole for a product	+	Increased expenditure	-
Alle information on one document	+	Additional information is neverthe-less required (e.g. regarding type, location, and responsibility of filing)	-
Additional expenditure	-		

Fig. 6-3: Types of marking **+ =** adv./ **-** =disadv.

6.2.2 Marking of Products and Product Equipment

In general it is not required and not practical either, to mark the product itself or the packing or transport unit respectively, containig such products, in order to indicate, that this is a product having DwSpA. This information does not mean anything to those receiving the product, such information represents an unnecessary expenditure only. If DwSpA pertaining to goods are delivered to the customer, it is recommended that they are handed out to the customer separately.

It is important in any case, to allocate the DwSpA to the delivery lots, delivery periods, marking of manufacturing date or the like of the corresponding products in a suitable manner.

But it has been strongly recommended to mark the products (as far as technically feasible) and/or the packing units with regard to:

- Part number (identification of product) and
- Allocation to a certain manufacturing period, e.g. by:
  - manufacturing date
  - batch relation
  - shift designation
  - modification status
  - running number (serial number).

This marking is required, in order to allow the interrelation between the products and the corresponding DwSpA (traceability).

In general it is not required to mark the machinery and equipment (hardware) on site that produce quality characteristics, proof of which must be conducted with special archiving. If special specifications and/or personnel qualifications have to be observed with regard to the operation and the actuation of this equipment, then this should be defined for practical reasons in the appropriate documented procedures and work plans (= DwSpA), and compliance should be proven (= DwSpA). The specific archiving of these proofs, such as analysis of machine capability, test equipment capability, process capability, maintenance, calibration of test equipment, training of personnel etc. does not depend on the marking of the corresponding hardware.

6.3 Examples for Documents Proving Compliance With Quality Requirements

Steps of Process	Quality-Related Documents
Sales and Marketing	Market analysis Contracts List of specifications
Product Development	Project release List of specified functions Drawings Bill of materials Results from design reviews Test results Liste of standards used System / design FMEA External test results Instruction of personnel
Qualification of - Subassemblies -Final products	Qualification procedures plans Checklists Inspection and test results Release reports
Validation	Test reports from practice
Qualifications of Purchased parts	Qualification procedures plans Initial sample reports (VDA 2) Individual release reports Check-lists
Process Development	Process FMEA (VDA 4.2) Process procedures plan Process data sheet Manufacturing plan Inspection plan Documented work/inspection procedures
Process Evaluation	Machine capability analysis Process capability analysis (VDA 4.1) Process release
Customer Release	Design release Initial sample test report (VDA 2)
Process Control	Control charts (SPC) Process data records Inspection results Minutes on corrective measures

Steps of Process	Quality-Related Documents
Tool Supervision	Measuring records
Preventive Maintenance	Maintenance records
Receiving Inspection	Inspection certificates Q documentation at the supplier Results from Receiving Releases
Intermediate Inspection	Control charts (SPC) Quality supervision charts Checklists Pareto analyses Single value records Statistical evaluations
Final Inspection	Results from individual inspection Summary of inspection results Statistical evaluations Limit value samples Proof of current supervision of inspection equipment
Audits	Audit reports and lists of measures on pro- duct, process, and system audits (VDA 6)
Qualification of Personnel	Proof of compliance with requirement pro-files according to position specifications
Training	Training planning Particiaptioin certificates Schulungsnachweise Proof of periodic instruction at workplace
Supervision of Inspection Equipment	Records regarding inspection equipment supervision Inspection equipment analyses Documentation of referenceability to master equipment devices
Corrective Measures	Special releases Catalogue of corrective measures 8D reports

Figure 6-4: Examples for the documents on the steps of process

Figure 6-4 shows at hand of an example the quality requirement documents and records that may serve as proof of compliance with quality requirements and with the correct function of the QM system.

Remark: Special archiving of all named documents and material is not required at all. The selection will be conducted in appropriate accordance with the individual product and the reason for the demonstration of proof.

6.4 Possibilities of File Backup in EDP Applications

File backup should be conducted, when a new working procedure on the document may cause a data loss at the latest.

- Backup procedures should be conducted in regular time intervals during registration of data, in order to avoid data loss, (e.g. operation-related file backup: Data should be stored upon completion of each individual operation, or be transferred to the central EDP Host).

- Recently established documents/files should generally be secured by backup before being printed out.

- Never overwrite a preceding backup copy with a new backup copy.

- Always keep backup copy separate from the original. It has therefore been recommended, to use two alternating storage medium sets for the backup copies.

There are different storage possibilities for file backup, depending on the type of hardware equipment and the scope of data to be secured:

- Diskette
- Exchangeable hard disk
- Digital audio tape (DAT)
- Streamer tape
- Exchangeable optical disk.

File backup in network systems is commonly executed automatically by a server. This periodic file backup is in general not sufficient in networks with large flow of data. The ”data reflection” system has been recommended in such cases. The information to be secured are continuously stored parallel to each other on two independent storage media. Thus, the second storage medium may be used in the event of a failure of one storage medium..

In the PC area today, the streamer is the most commonly used means of file backup besides the diskette. Increasing usage has also been observed with CD-ROM, where the writing is executed on an optical basis, and the data cannot be altered any more.

Another aspect that has often been neglected is the lifetime of the data carrier. Two criteria must be observed, in order to assure the readability of the stored information during the entire period of archiving:

1. Electronic storage media undergo a quality loss over the time.

2. The hardware and software required for the reading of the data must be available during the anticipated archiving period.

With regard to data service life, you should follow the recommendations of the storage medium manufacturers. The stored data must be transferred in time (refreshed) to a new storage medium if required (safe data service life shorter than anticipated archiving period).

In addition, the future readability of the information stored on electronic storage media must be secured in case of a change of hardware and software. The corresponding equipment must either be kept available in the future or, a transfer of the data under loss hazard must be conducted to storage media that are readable by the new equipment. If one decides for the old equipment it must be observed, that any failure of the old equipment includes the hazard of loss of readability of these stored files. It has therefore been recommended for this case, to keep the appropriate hardware and software equipment available in several numbers.

When archiving electronically stored data and information, the specific storage conditions for the storage media (e.g. protection from magnetic fields) must be considered besides the regular requirements regarding rooms for archiving. In cases of doubt, the recommendations of the storage media manufacturers may be helpful.

6.5 Selection Procedure for DwSpA

6.5.1 Procedure of Selecting DwSpA

A systematic, process-oriented procedure may be helpful for the selection of DwSpA. Figures 6-5 and 6-6 represent an appropriate procedure.

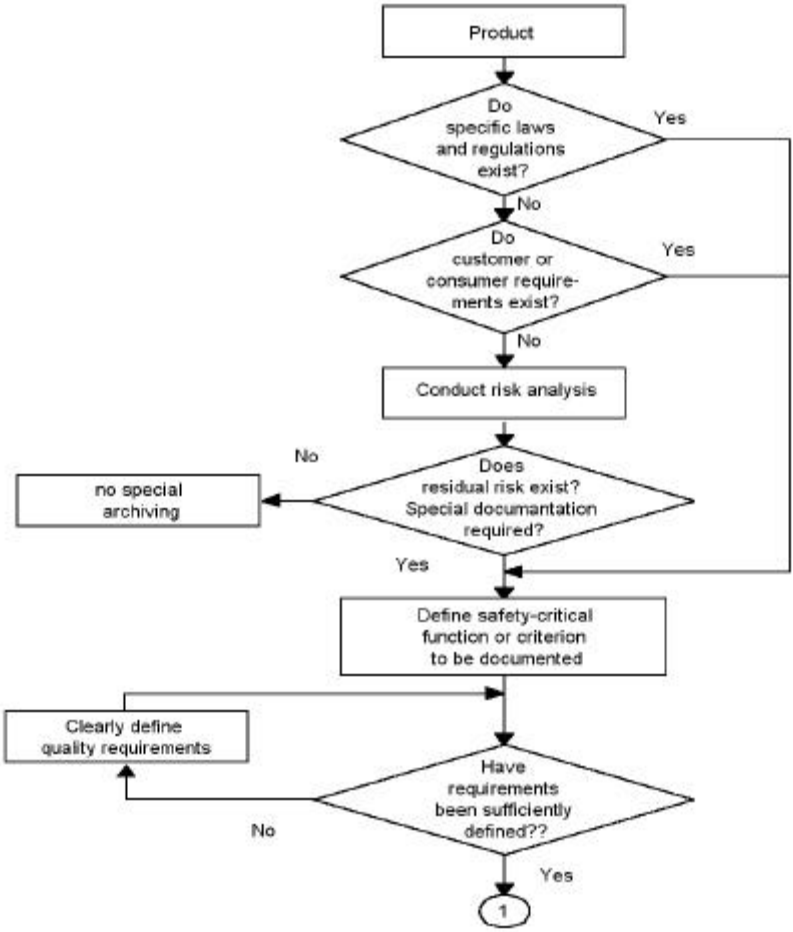


Figure 6-5: Flow chart for the selection of DwSpA, Part 1

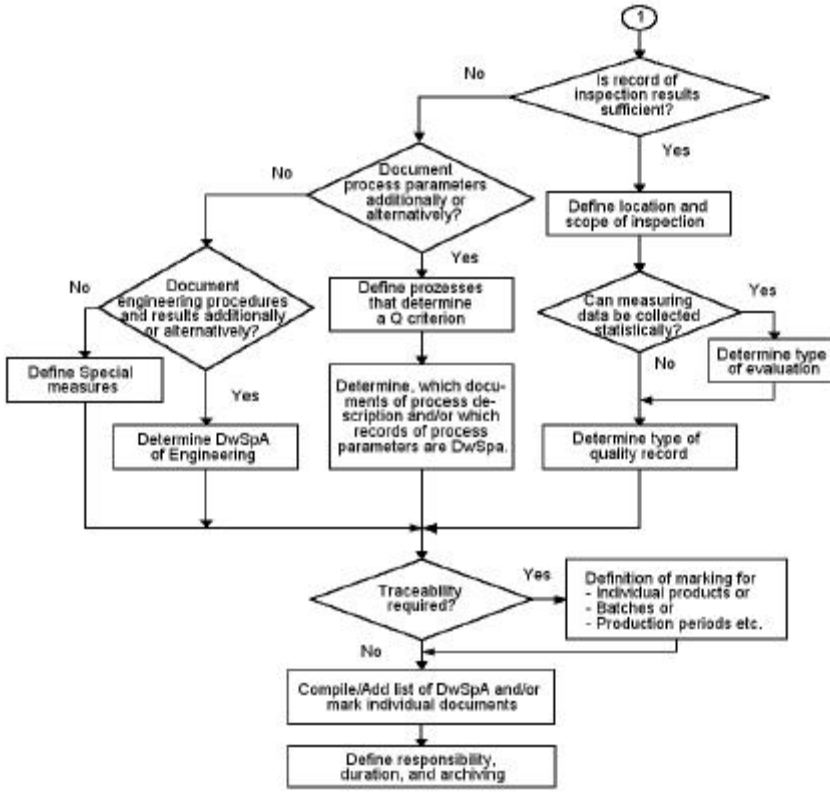


Figure 6-6: Flow chart for the selection of DwSpA, Part 2

6.5.2 Criteria for the Specification of Special Archiving

In cases where special archiving has not been prescribed externally (by regulations, laws, customers), the risk of a damage that may cause a recall and/or product liability claims can be estimated by using an FMEA-type evaluation of various criteria, as shown at hand of Figure 6-7 as an example. This may be used to deduct the necessity for special archiving of certain characteristic figures and/or procedures.

Criterion A	Criterion B	Criterion C
Degree of Safety Reduction	Probability of Occurrence of Non-Conformities	Probability of Discovery of Non-Conformities
1 low	1 low	1 high
No or low reduction	Design/manufacturing process corresponds to a status, for which no/an insignificant number of problems are known	Non-conformity has been discovered during manufacturing process.
2 medium	2 medium	2 medium
Safety reduction. Accident cannot generally be excluded.	Design/manufacturing process corresponds to a status, for which non-conformities cannot be excluded.	Probability exists, that the non-conformity will be discovered during the manufacturing process
3 high	3 high	3 low
Failure will most likely lead to accident with personal injuries	Design/manufacturing process is new, no experience yet so far	It is almost unlikely, that the non-conformity will be discovered during the manufacturing process.

Figure 6-7: Selection criteria for DwSpA

The determined number combination can for example be allocated to a statement in a table (Figure 6-8), showing that in this case special archiving must be considered. In general, the combinations that are not shown do not lead to the necessity of special archiving.

Criterion A	Criterion B	Criterion C	Special archiving to be considered
2	2	2	yes
all other combinations which contain number 3			yes

Figure 6-8: Decision criteria

This allocation can represent examples only, that should be modified for specific company reasons and on a case-by-case basis.

6.5.3 Checklists for the Treatment of Products With DwSpA

The following checklists for the treatment of products and characteristics anticipated for specification of DwSpA (Figure 6-9 and 6.10) represent proposals that must be adapted for specific company reasons and on a case-by-case basis.

Running No.	Requirement	Completed Yes	Completed No
1	Definition of specification is clear and can be tested		
2	Set-up of a documentation plan (possibly as alternative to 3 through 5)		
3	Marking of bill of material as DwSpA		
4	Marking of drawing as DwSpA		
5	Marking on the drawing of the characteristics to be documented		
6	Conduct FMEA		
7	Marking as DwSpA of the manufacturing plans and the processes/process parameters to be documented		
8	Plan manufacturing processes such, that the quality requirements to be documented can be met safely (process capability)		
9	Establish QM plan		
10	Marking as DwSpA of the inspection plans and inspections included therein, the results of which must be documented		

Running No.	Requirement	Completed Yes	Completed No
11	Definition of inspection equipment, by which the characteristics are registered with sufficient safety of inspection (capability of inspection equipment)		
12	Definition of the frequency of inspection (under consideration of the manufacturing safety) with statistical safety such, that compliance with the limit values can be proven over the entire manufacturing period.		
13	Set-up of specifications for type and scope of supervision of manufacturing equipment and of the part-related setting figures.		
14	Assurance of employee instruction at the wotkplace		
15	Establish initial sample test report for dimensions, function, material		
16	Assurance of permanent supervision of the inspection equipment and devices		
17	Specification of organizational measures assuring the separation of parts on which non-conformities have been discovered		
18	Specification of documentation procedure for corrective measures		
19	Define, which documents should treated for archiving in which way (DwSpA)		
20	Check, if the documents selected for special archiving comply with the specified reqirements regarding the demonstration of proof		
21	Permanent checking of the documentation regarding its correct execution (audit)		
22	Assure, that design or manufacturing modifications regarding characteristics to be documented will automatically be subject to the procedure specified in this checklist		
23	Define product reviews		

Figure 6-9: Checklist for the treatment of products with DwSpA - in-house production

Running No.	Requirement	Completed Yes	Completed No
1	Inclusion of supplier in decisionmaking to specify the necessity and scope of the documentation (information on product application, legislatory situation, safety relevance etc.)		
2	Definition of clear and inspectable specifications for the supplier		
3	Marking of the documents as DwSpA, also at the supplier, e.g. drawing, bill of material, documentation plan		
4	Marking of the characteristics to be documented on the documents		
5	Supplier evaluation under specific consideration of their capability to manufacture safely those products requiring DwSpA, and to conduct the documentation correctly in accordance with VDA Volume 1		
6	Provide supplier confirmation, that he will comply with the requirements regarding product and documentation		
7	Planning of assurance of the quality delivered. E.g.: Receiving inspection, proof of process capability by the supplier, plant certificate with lot-related measuring results		
8	Specification of measures for identification and traceability (customer and supplier jointly)		
9	Supplier information about product liability risk		
10	Agreement on other requirements		

Figure 6-10: Checklist for the treatment of products with DwSpA - purchased items

6.6 Traceability

The expenditure for special archiving in order to assure the traceability is practical and economical for all involved, only if the traceability has been assured over the entire chain of production from the sub-supplier to the supplier and the manufacturer and further to the sale of the vehicle, see Figure 6-11.

Elements of the Chain of Production	Step of Process	Characteristic to Be Pursued	Allocation Criteria	Records
Initial supplier	Manufacture of steel	composition of alloy, crack-free structure, texture	Batch number	Plant inspection certificate
Parts manufacturer	Manufacture of rack	Surface hardness, strength, crack-free structure	Batch number, Manufacturing lot	Process data Ispection results
Supplier, Module supplier, System supplier	Manufacture of steering gear	Test results, functional values, functional safety criteria	Manufacturing lot, Manufacturing date, Idividual part number	Design data, Inspection resulls Vehilce type plate
Automobile manufacturer	Installation in vehicle	Functional safety	VIN	Sales documents

Figure 6-11: Schematic overview of traceability - Example: Steering gear

ANNEX

1 Abstracts and Comments Regarding Laws, Contracts, Standards, and Association Requirements

As described in Par. 3, the reasons for a demonstration of proof are often founded in laws and contracts, which in turn refer to some extent to other standards and association requirements. To give support for decisionmaking in this regard, below are some of the most important requirements including wording and interpretation, that have been applicable at the time of printing.

1.1 Requirements from Laws and Contracts

1.1.1 Requirements on Operational Safety

Laws are describing requirements relating to motor vehicles that are participating in road traffic. They include among others the definition of liability for non-conformities and consequential damage, and minimum rules for type approval and manufacture. In general, the minimum rules for the manufacturing safety are described in these laws as general requirements, and their precise scope regarding demonstration of proof has not been defined. For these reasons, precise definitions will always require a risk evaluation of the entire corresponding process too.

Among these laws is for example the German Road Traffic Homologation Law (”StVZO”), § 30:

> *”(1) Mot or vehicles must be designed and equipped in such a way, that*
>
> *1. during their common use in road traffic nobody will be damaged or, more than unavoidable incur any hazard,be impeded or annoyed,*
>
> *2. the occupants will be protected as much as possible, specifically in accidents against injuries, and that the extent and the consequences of injuries remain minimal as much as possible.*
>
> *(2) Vehicles must be designed and maintained with regard to road protection.*
>
> *(a) Vehicle components that are important for road traffic or operational safety and that can easily be used up or damaged, must be such that they can be checked in a simple manner and easily be exchanged."*

The requirements of the ”StVZO” apply above all to products that have been brought into road service for the first time. In this regard, the manufacturer is responsible for the condition of a defect-free product. His responsibility is based on the laws, among others on the Product Liability Law or the Civil Law (BGB § 823) in general. These laws describe the liability of the manufacturer for damages that any user or third party may incur, due to insufficient safety of use of the product, e.g in § 1 Subpar. 1 ”ProdHaftG” dated 01 January 1990:

> *”In case of the death of a person, in case of injury to his/her health or in case of property damage, due to a defect of the product, the manufacturer shall be liable for compensation of the damage resulting thereof to the injured party ....”.*

In Europe, minimum rules have been defined for type approval for compliance by the manufacturer, e.g. by the General 70/156/EEC, version 92/53/EEC, Par. 10, Annex X, Initial evaluation, Section 1.1 through 1.3:

> *”Before granting a type approval, the approving authority of a member state will verify if the necessary measures have been observed and if procedures are available, to assure an efficient control of compliance of the manufactured components, systems, independent technical units or vehicles with the approved type in each case.”*

Other motor vehicle requirements in the national legislation worldwide are defined for example in the USA in:

- US safety regulations: FMVSS (Federal Motor Vehicle Safety Standards), based on the National Traffic and Motor Vehicle Safety Act of 1966, issued by the National Highway Traffic Safety Administration in the USA. These regulatioins include for example the administrative rules and requirements regarding the entire vehicle, in analogy to the above-mentioned EU Directives.

- Die US environmental protection regulations (Title 40, Chapter 1) Environmental Protection Agency, Subchapter C: Air Programs. They include e.g. the administrative rules and requirements for emissions: Part 86 - Control of air pollution from new and in-use motor vehicles.

1.1.2 Requirements on Documentation

For Europe, minimum rules to be met by the manufactuarer have been defined for example in the General Directive 70/156/EEC, version 92/53/EEC, Par. 10, Annex X Section 2.1 through 2.3.3:

> *"Each vehicle, system, component or each technical unit which has been approved based on this directive or on an individual directive must be designed in such a way, that it is in conformity with the approved type and that the regulations of the present directive or of an individual directive are met, which are included in the complete list in Annex IV or in Annex XI. The approving authority of a member state granting a type approval, verifies in coordination with the manufacturer with regard to any approval, that suitable precautionary measures have been taken and that written test procedures exist, in order to be able to conduct tests in defined intervals or suitable reviews including the tests, which may be defined in individual directives, in order to assure continued conformity with the approved type.* ***It is above all the duty of the holder of an approval to assure, that test results are recorded and that the records and the related material remains available over a period of time to be agreed with the approving authority. This period should not exceed 10 years."***

For the USA appropriate regulations for the demonstration of conformity of production with the type approval are included in the National Traffic and Motor Vehicle Safety Act of 1966, Issue 1082, revised until 31 October 1988, Section 1, Paragraph 112 (b), Sheet 23:

> *"Each motor vehicle manufacturer must* ***keep such material on files and compile such reports that can reasonably be requested by the Department****, in order to allow the Department to determine if a manufacturer has acted in compliance with this Section or with any regulations, administrative rules including the orders published therein....".*

For Australia for example, the Australian Motor Vehicle Certification Board, Conformity of Production-Manual-Circular 0-13-1, Item 2 is applicable to the conformity of production with the type approval:

> *"Each manufacturer must provide measures for quality assurance, among others:*
>
> *d) specific controls for safety-critical parts*
>
> *(f) control procedures for the documentation:*
>
> *During Conformity of Production (COP) reviews, i.e. the review of the products with regard to conformity of the manufactured products with the individually approved product, the manufacturer must* ***demonstrate proof at hand of documents and quality records".***

Large customers, such as the Federal Armed Forces or Nato partners, Postal Services and increasingly freight forwarding companies, car rental companies etc. are making reference in their contracts to quality assurance systems according to AQAP 100 and following or DIN EN ISO 9000 and following. The conclusion of such contracts may be regarded as a requirement that goes without saying in a long-term, partner-like cooperation. Examples for contractual definitions are:

- The German Industry Association (”BDI”) - Governmental Standard Agreement, e.g. initial evaluation of quality assurance in production and assembly (corresponds to Annex X, Section 1 regarding Article 10 of the Council Directive 92/53/EEC). Abstract from Par. 1.3 Quality Records:

  *”Definition of the required measures, that the **quality records and QA proofs** must be compiled correctly in all areas of the company, in order to protect them against loss.”*

- The standard agreement of the Federal Armed Forces (”BWB”), (Nato requirement regarding an industrial inspection system according to AQAP 100 and following). Abstract from Par. 203b Records:

  *”The contractor must **keep records on all conducted tests**, which are used for conformity purposes. The records must include, as far as required, article designation, lot, type and number of findings, type and number of non-conformities found, accepted and returned volume as well as corrective measures conducted. The records must be stored and be available upon request.”*

- VDA Recommendations, dated 15 August 1995 ”General business terms for the procurement of production material and spare parts, intended for automobiles”. Abstract from Par. IX.3:

  *"In case of motor vehicle components with special marking in technical documents or based on special agreement the supplier must in addition **maintain special records defining**, when, in which way, and by whom the delivered items shall be inspected with regard to those characteristics that must be documented, and which are the results from the required quality tests".*

1.2 Requirements from Standards and Orders from Public Authorities, and from Associations

Besides the requirements by law, there are those from customers too, that require compliance by contract with standards and association rules regarding quality management issues. In this case, they cannot only be regarded as recommendation, but finally as requirements. The same applies to the observation of the scientific and technical state of the art.

In most cases compliance with standards such as DIN EN ISO 9000 and following is required. Thus, the compilation of documents among others and of quality records in view of demonstrating proof of compliance with the quality requirements and with an efficient functioning of the quality management system have become a duty. This duty to demonstrate proof applies in general to all products and processes in manufacturing and when rendering services..

DIN EN ISO 9001 through 9003, Issue August 1994 prescribes in Paragraph 4.16 ”Control of Quality Records” :

> *"The supplier must establish and maintain documented procedures for the marking, collection, registration, accessibility, filing, storage, updating, and disposal of quality records".*

Before granting a type approval for a motor vehicle or a component, the approving authority, e. g. the Federal Motor Vehicle Agency will verify, if the manufacturer applies a quality management system, by which conformity of production has been assured. This requirement regarding the quality management system of the manufacturer and his systems or component supplier has been defined by the Federal Motor Vehicle Agency in its ”Catalog of Requirements for the Justification of the Manufacturer’s Capability” dated August 1993. In this regard, the manufacturer must assure according to Paragraph II, Subpar. 1.1 through 1.3:

> *"...that a standardized QA system according to EN 29001 or EN 29002 (or ISO 9001 or ISO 9002, or actually DIN EN ISO 9001 or 9002 respectively) or another comparable standard that has been adapted to the requirements is available in the part of the manufacturing operation working for him. In addition, he must assure and demonstrate proof of the efficiency of this QA system by appropriate measures..*
>
> *...that the manufactured products will be inspected with regard to their approval conformity before bringing them into service by using suitable random sample plans (product inspections).*

...that the manufacturer presents procedures that assure, that in case of discovery of non-conformity of products, these products cannot be brought into service operation or that products used in service operatioin can be recalled again."

Association recommendations, such as the VDA series of publications "QM in the Automobile Industry", Volume 6, Part 1, 3rd edition, "Quality Management System Audit According to DIN EN ISO 9001 and DIN EN ISO 9004", are describing QM systems including all elements, and provide support for interpretation and definition. Many manufacturers in the EU are using this VDA Volume as their contractual basis. There, this reads as follows:

"The quality management requires the recording of quality-relevant data, in order to demonstrate compliance with defined quality requirements. Therefore, their identification, collection, order, distribution, maintenance, and storage must be considered. The ability to find stored records again, and theior hierarchical order must be assured at all times.

Related quality records from suppliers must be considered in the same way".

In this regard, in VDA Volume 6, Part 1 for example, in QM element 20 the following questions are found:

- *Have responsibilities and procedures beed defined for the collection and checking of quality records?*
- *Are there procedures and responsibilities for evaluation and distribution of quality records?*
- *Are there definitions on where, how, and how long quality records will be stored?*
- *Are there definitions on how quality records will be made available to the customer, if this has been agreed upon by contract?*

2 Schematic Overviews

The Figures below show the consequences of defective products (Figure A2-1) and the major differences in liability for consequential damage based on defective products (Figure A2-2).

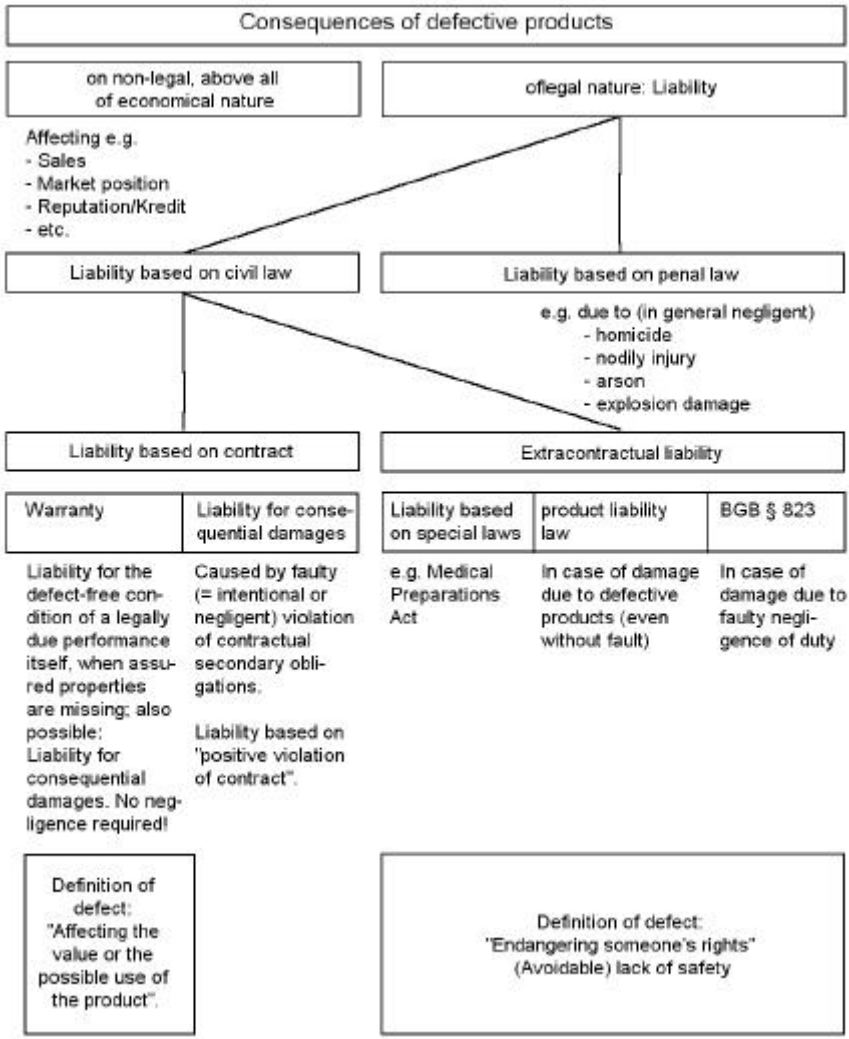


Figure A2-1: Consequences of defective products

Liability bases / Liability differences	Contractual liability - Liability from positive violation of contract	Tortious liability according to § 823 BGB	Liability according to the Product Liability Law
Liability prerequisites	Violation by default (= intentional or by negligence) Violation of a **contractual** (secondary) duty and damage caused thereof	Violation by default (= intentional or by negligence) Violation of the general duty of care toward third parties (i.e. not to violate the rights of third parties) and damage caused thereof	Defective product (default is not important!) and damage caused thereof
Damage: Damage to be compensated	all direct and indirect damage, also pure property loss	All (direct and indirect) damage to those rights **that have been protected by § 823 BGB**, including compensation for pain and suffering	All direct and indirect damage due to death or personal injury as well as to "private" matters
losses that cannot be compensated	Immaterial damage (compensation for pain and suffering)	**Pure** property damage	Immaterial damage (compens. for pain and suffering); damage to industrial property, facility operations or to public property
Liability of vicarious agent or employee	Liability for fault of such persons is treated like liability for own fault	Liability only if fault of such persons also applies to business management/ employer, i.e., in case of incorrect selection, instruction or supervision (§ 831 BGB); such a fault is being assumed by the law - the business management must prove ist innocence	Unlimited, because any fault is not important, but the defective-ness of the product alone
Agreed exemption from liability (exclusion or limitation of liability)	Under certain conditions at least partially possible wiithin the scope of an appropriate agreement with the injured party	As with contractual liability (of minor importance in practice, since damaging and injured party do in most cases not know each other, and can therefore not conclude any agreement)	Not possible
Statute of limitations	In case of claims due to damage having close relation to insufficient performance ("damage due to shortcoming"): 6 months; in case of "more distant" consequential damage: 30 years. Begin of term: Acceptance or delivery of performance	3 years (as of knowledge of the injured party about the damage and of the injuring party); at the latest: 30 years after occurrence of the action that caused the damage	3 years Begin of term: When the person entitled acquires knowledge of damage, of the product defect and of the person liable, or when he/she sould necessarily have acquired the knowledge
Expiration	No expiration due to pure elapsed period of time	No expiration due to pure elapsed period of time	10 Jahre years after bringing into service of the product

Figure A2-2: Schematic Overview on Major Differences in Liability for Consequential Damage Due to Defective Products

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