

INTERNATIONAL STANDARD

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Technical product documentation — Document management

Documentation technique de produits — Gestion de documents

Technical product documentation — Document management

1 Scope

This International Standard specifies basic rules for the management of technical documents.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10209-1, *Technical product documentation — Vocabulary — Part 1: Terms relating to technical drawings: general and types of drawings*

ISO 16016, *Technical product documentation — Protection notices for restricting the use of documents and products*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 10209-1 and the following apply.

3.1

analysis

part of the product development process where a specification of requirements is prepared

3.2

approval phase

stage in which the document content is formally checked and approved

3.3

archive master

document replica for long-term storage in a trusted encoding format

3.4

archiving phase

stage in which product documents are removed from the storage of active documents to an historic archive

3.5

authorization

⟨of a user⟩ privileges that give access to designated activities

3.6

basic design

part of the product development process where one or more design proposals are evaluated and the basic documentation for design is prepared

3.7

conceptual design

part of the product development process which includes the preparation of design specifications and design proposals for a product

3.8

creation phase

stage in which the design documentation work is carried out

3.9

detailed design

part of the product development process which includes the preparation of the final product definition

3.10

document

fixed and structured amount of information that can be managed and interchanged as a unit between users and systems

[IEC 82045-1:2001]

3.11

document replica

true or close-to-true copy of an original document

3.12

document issue

identified version of a document

3.13

document status

step or stage in the life-cycle of a document issue

3.14

original document

document onto which the technical description or definition of a product is recorded and which forms the base for future changes

3.15

release, verb

making an approved document available for its intended purpose

3.16

release phase

stage in which a document is released

3.17

replica fidelity

level of ability of a document replica to promote the information of the original document

3.18

revision notice

document part or separate document recording all the revisions made on a product document

3.19

revision phase

stage in which changes to product documents are made

3.20

specification of requirements

compilation of market, authority (e.g. laws, regulations, directives) and company related requirements

3.21

storage/active phase

stage in which the active product documents are stored

3.22

signature document

copy of the original document with the addition of approval required by customer or authority, constituting an original for a certain approval stage.

3.23

viewing copy

document replica for viewing, commenting and for production of hard copies

4 Original and reproduced documents

4.1 General

The following descriptions are used in order to assist in the application and understanding of the documentation system:

4.2 Original document

An original document is a document that intentionally has no identified source document. A single original document or a structure of associated originals shall constitute the technical definition or description of a product and shall also form the basis on which changes are made during the lifetime of the product.

Each approved original document shall be filed in an original storage archive (vault) to which document access shall be controlled through check-in/check-out procedures. A computer-based original document shall be stored in an identified file format on a trusted medium (e.g. magnetic or optic). In the manual production of documents, the medium for representation data, in the form of figures and/or text, shall be suitable for reproduction, e.g. paper or draughting film. Any revision required shall be based on the original document.

When and if the preferred file format can no longer be supported (e.g. vector format), the original status shall be transferred to a file format intended for long-term stability (e.g. raster format), generally with an accepted loss of information (see 4.5). The transfer to another file format may also depend on local, company procedures.

4.3 Signature document

Original documents require ordinary approval procedures, but may also need approval by customer or authority. A signature document carries this additional approval. This document is usually paper-based, being a copy of the original document, and shall not be subject to any form of change without the stamp and signature it may require for approval.

4.4 Viewing copy

A viewing copy is a document replica used, e.g. for viewing, commenting and for production of hard copies (printed replicas). In computer-aided design this can be a raster document for on-screen viewing or an aperture card directly or indirectly produced.

4.5 Archive master

In computer-based documentation a document replica (see 4.6) should be produced for long-term storage in a trusted neutral format. The archive master shall be retrievable and reproducible for a defined period of time (e.g. depending on the product's lifetime). The representation shall be openly specified and forwardly independent of tool versions.

NOTE Typical formats for digital archive masters are TIFF raster, SGML, XML and STEP.

4.6 Document replica, replica fidelity

A document replica is a true or almost-true copy of an original document. A replica may have lost information relative to its source. The degree of fidelity shall be classified due to the ability of the document replica to promote the information of the original document.

Values of replica fidelity shall include

- clone (exact copy),
- equivalent (with loss of information, for a dedicated purpose equivalent), and
- essential (some properties of the original may have been lost, like colour)

5 Phases in the design documentation work

5.1 General

The following description shows where different documents can be generated within the design cycle. The activities during the product development process can be divided into *analysis*, *conceptual design*, *basic design* and *detailed design*, as described in the example below. See Figure 1.

Normally, an initial task will be to establish a specification of requirements, compiled and evaluated with the requirements from the market, authorities and the company itself.

Based on this, design specifications are produced as a base for further development. These may indicate possible functional solutions and/or shape representations, which will be the basis for one or more proposals to be evaluated. The result of the evaluation constitutes the basic documentation for design.

During the detailed design the documents are finalised for its intended purpose and formalised to more strict rules for document management.

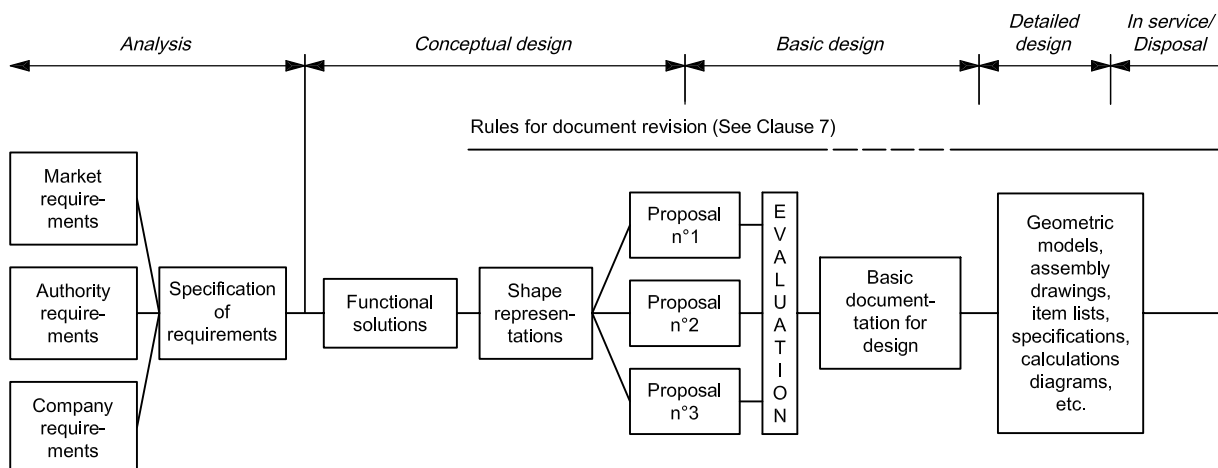


Figure 1 — Product development process

5.2 Management of technical product documents

Throughout the different stages of the design documentation process data shall be stored, moved and presented according to strict rules. The document management process is divided into different phases, shown with their respective activities, in Figure 2.

The transfer of data from one phase to another shall be made in accordance with established procedures adapted to the need of the activity. These procedures shall be well documented.

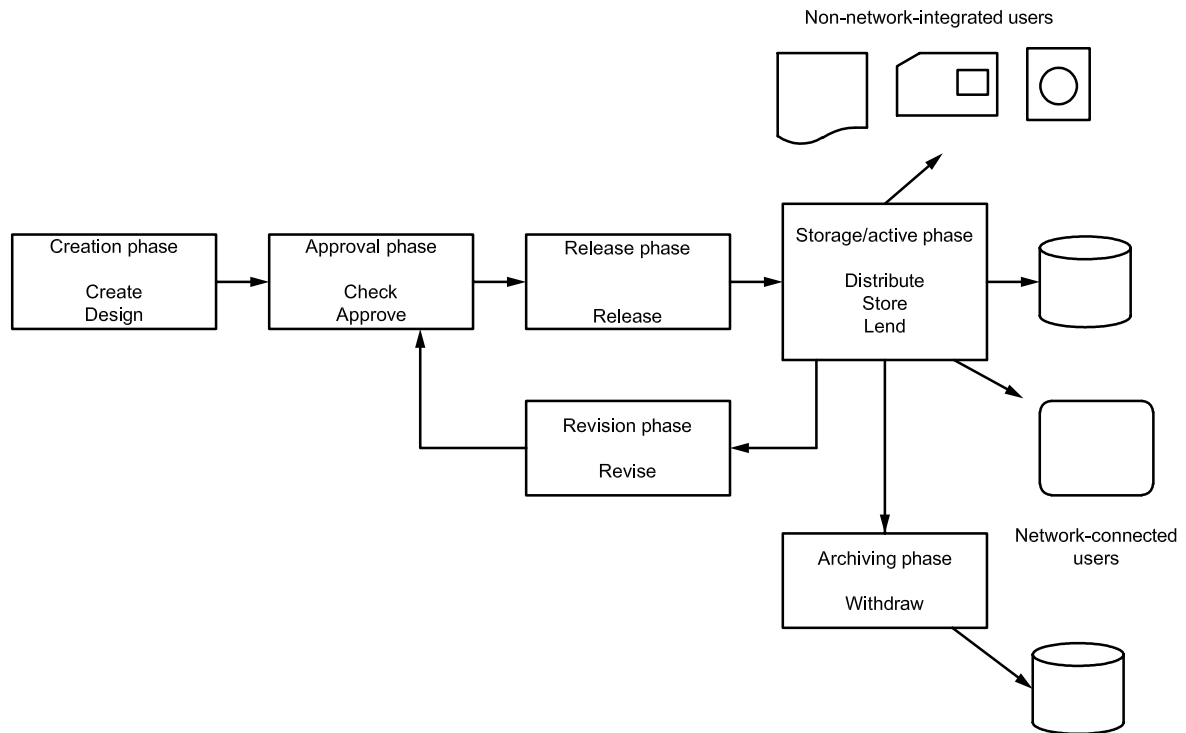


Figure 2 — Phases in the design documentation work

5.3 Creation phase

The phase in which the actual content of the document is established is termed the “creation phase”. Documents exist in this phase from document status “in preparation” until the “in review” status is initiated. A document in the creation phase is the property of its creator. The document shall therefore be considered preliminary; for example, it shall not be used for binding agreements.

If special business requirements demand the early usage of documents in this phase for binding agreements (e.g. ordering of raw materials or design of tooling for long lead-time items) a clear indication shall be given to which extent the usage for dedicated purposes is possible.

Any use of the document shall be checked with the creator.

5.4 Approval phase

When the creator considers the document to be finished the approval phase shall be initiated. This is indicated by the document status “in review”. A document with this status is still the property of the creator and the same restrictions as for “in preparation” apply regarding its use. If the document is rejected it shall be brought back to the creator and to the document status “in preparation” before necessary modifications may be made.

The final status of the document in the approval phase is “approved”. If necessary this shall be shown as a separate document status indication. In other cases the document shall be directly transferred to the release/issuing activity.

5.5 Release phase

Release is an activity independent of approval. The timing can therefore be chosen to coordinate with other document issues and other activities within the project.

When a document has been checked and approved according to the procedures within the *responsible department's* organization it can be released. This is the department responsible for the content of the document within the organization of the legal owner.

A released document is officially valid and is allowed to be used for its intended purpose. This shall be indicated by the status “released”. In local environment, specific naming conventions for this status could occur and shall be clearly defined.

5.6 Storage/active phase

The storage/active phase means that released documents shall be stored and be available to authorized users for reading and copying.

A normal form for distribution is when a document is made available for users within a dedicated system. Attachments to electronic mail or alternative media (aperture card, paper printout, tape, diskette, CD, etc.) may also be distributed to users who do not have on-line distribution or are not integrated in the network.

The distribution may be supported by a document list, showing all documents which are released simultaneously, usually belonging to the same project, equipment, etc.

5.7 Revision phase

Revision implies that a clone of a stored document is checked out, raised in revision and assigned the status “in preparation”. The original document is still valid and available to users but the system shall provide a warning “under revision” that a revised version is expected. It is then up to the user to check with the responsible unit and decide whether to use the existing version or wait for the expected revision. See Figure 3.

The copy being amended has a new revision index and the status text “in preparation” until its approval phase is initiated. When the revision is approved and released the document shall be transferred to the storage/active phase.

When a document is released and distributed for further use, formal rules and procedures describing how changes are managed shall be introduced. For detailed revision rules, see Clause 7.

5.8 Archiving phase

The archiving phase shall be initiated by the removal of documents from the storage for active documents to an archive for archive master documents. The access time could be considerable. This might involve

- previous versions of active documents,
- replaced/superseded documents,
- withdrawn documents, or
- documents for obsolete products.

6 Document life-cycle status

During the different phases a document can exist in different document statuses as shown below. The status levels shall be shown via document printout or an alternative system function.

- *In preparation* means that the document exists but is not yet officially released for its final use.
- *In review* means that the document has been prepared and is subject to review, endorsement, checking and approval.
- *Approved* means that the document is suitable for release but is not yet officially released for its intended use.
- *Released* means that the document has been prepared, reviewed, checked and approved. The document is allowed to be used for its intended purpose.
- *Replaced* means that the document is still available but has been replaced or superseded by another.
- *Withdrawn* means that the document is no longer available as an active document.

Figure 3 shows the process flow for a document as it passes through the different life-cycle statuses. In addition to the statuses defined above a locally defined process with smaller steps in the document lifecycle may occur.

8 Protection of information

8.1 General

Procedures defining levels of information access by users shall be applied. In addition, there may be specific requirements to define procedures for the allowed purpose of the access and the allowed environment the access is granted, managed and/or executed by.

These procedures should cover single user actions as well as system functions.

8.2 Authorization

Procedures shall be established defining the authorization to create/design, read/copy, check/approve and revise document contents, and to transfer documents to archive. See Table 1.

Table 1 — Examples of access to documents in different document life-cycle statuses

Life cycle of a document	Users within the organization of the creator	Normal users in accordance with agreed rules	On special request
In preparation	X		
In review	X		
Approved	X		
Released		X	
Replaced			X
Withdrawn			X

When using computer-based systems, the identification of users shall be controlled by sufficient methods, e.g. user identification (user ID) and passwords (electronic identification card, etc.) enabling authorization procedures to be executed.

8.3 Protection notices

In order to prevent improper use of documents a protection notice according to ISO 16016:2000 shall be used.

Annex A (informative)

Typical rules for document revision

A.1 Simplified rules for revision

Simplified rules for revision are primarily used by the issuer of the document in connection with design changes that can affect parallel or subsequent development activities like

- changes in the design prerequisites,
- new design as a consequence of inadequate function, space or quality,
- the desire of a manufacturer to introduce a design change in order to fit a certain manufacturing process, or
- a simplification of the product in order to reduce the costs of material.

The revision information may contain a description of the technical changes as well as information on how the changes affect the cost estimates.

A.2 Formal rules for revision

During the latter part of the product development documents are often widely distributed and, as a consequence, activities are initiated which require formal rules for revision. These may be divided into two types of revisions.

- a) Technical changes with requirement for *interchangeability* between the old and the new version. The **form, fit and function** of the component is not affected, and consequently the identification number is retained.
- b) Technical changes when the revised version and the old version of the component are no longer interchangeable. The changes affect the **form, fit and function** of the component and, consequently, the identification number is changed.

Documents in the storage/active phase are checked out for revision. A new issue of the document is prepared and a revision notice is established, clearly indicating

- the signification of the change,
- the position of the change,
- the reason for the change (if necessary),
- the consequences of the change,
- when the change is to become effective for concerned components, and
- other information necessary to document regarding the changes.

The revised product documents are transferred, together with the revision notices, to the approval phase for check/approval and then further on to the distribution phase, where the revised documents are copied and distributed to subscribers in accordance with a document issuing list.