

## 2.3 Quality documentation

### 2.3.1 Terms and abbreviations

A complete list of the definitions of all the terms and abbreviations used in PTB's quality documentation can be found in the [QP "Terms and Abbreviations"](#).

### 2.3.2 Objective

The priority objective of PTB is to ensure the quality of its scientific and technical services by implementing its quality policy. The services of PTB must comply with the purpose specified, they must meet the requirements of the customers, comply with the relevant legal regulations and standards, with the state of the art of technology and with the requirements of society; they must take environmental requirements into account, and they must be made available in an economically efficient way. A prerequisite for this is that all technical, organizational and human factors which might have an influence on quality are mastered. To achieve this aim, a quality management system was introduced and recorded at the PTB. This complies with both internal and external aspects. It allows PTB to prove its capability for quality to third parties, which contributes to confidence building. It is an internal tool for everyday work and, at the same time, a managerial tool to steer and optimize the level of quality according to cost-benefit and risk aspects.

The quality documentation covers the organizational structure as well as all the procedures, processes and means that are necessary for performing quality management within PTB.

The quality documentation serves to lay down the measures which are to ensure that the quality system is properly documented, applied and monitored. It takes into account PTB's long years of experience in the field of metrology, as well as the legal requirements (see [Annex 6.2](#)), the requirements of DIN EN ISO/IEC 17 025 and the recommendations of the Deutsche Forschungsgemeinschaft (DFG) to assure good scientific practice. For selected activities, also the requirements of ISO Guide 34, of DIN EN 45 011 or DIN EN ISO/IEC 17 065, respectively, have been integrated.

### 2.3.3 Structure

PTB's quality documentation is hierarchically structured and comprises several levels (see [Figure 2.3.1](#)). Its original is in the German language. In case of doubt, it will always be the German version of the quality documentation which will be valid, and not its translation.

#### Level I

At the top of the documentation pyramid there are - as basic documents which apply to the entire PTB - PTB's quality manual and PTB's quality procedures (QP). These lay down the tasks and areas of responsibility of the managerial staff defined in chapter 2.2 of PTB's quality manual.

This quality manual deals with the general aspects of the quality system, it specifies the basic regulations and objectives, and it gives an overview of PTB's service offering and of the legal, organizational, technical and local conditions.

PTB's quality procedures (abbreviated to: QP) are basic instructions which supplement PTB's quality manual and describe the general quality processes. They are valid for the entire PTB, i.e. for all employees and for all activities. In their specific areas, the individual divisions/bodies can add specific documents to these basic instructions. The QP have to be agreed upon in the "Quality Management Committee" (A-QM). They are aimed at involving all interested circles equally. Organizational regulations which are valid for the entire PTB - e.g. internal directions ("*Hausverfügungen*", abbreviation: "*HV*") - are made reference to in the QP if they are relevant.

#### Level II

Level II comprises the quality manuals of the individual PTB divisions, the quality manual of the body "IT Infrastructure" and the quality manual of the Certification Body. In these specific quality manuals, the regulations of PTB's overall quality manual and of PTB's QP, further details are specified for activities which are in accordance with the DFG recommendations for good scientific practice, with the legal requirements, and with the requirements of DIN EN ISO/IEC 17 025. For the production and certification of chemical reference materials, the requirements of ISO Guide 34 are taken into consideration additionally.

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The Certification Body adds additional requirements to the requirements of DIN EN 45 011 or of DIN EN ISO/IEC 17 065 ,respectively, taking thereby the respective legal requirements into account.

The quality documents of level II lay down the requirements for the content, structure and form of the activity-specific working instructions.

## Level III

The base of the quality system documentation pyramid is formed by the activity-specific working instructions for the Divisions 1 to 8, which concern the core services of PTB, and by the instructions for the Divisions Z and Q, for the certification body and for the body "IT Infrastructure", which concern the supporting processes with partly relevance for all divisions of PTB.

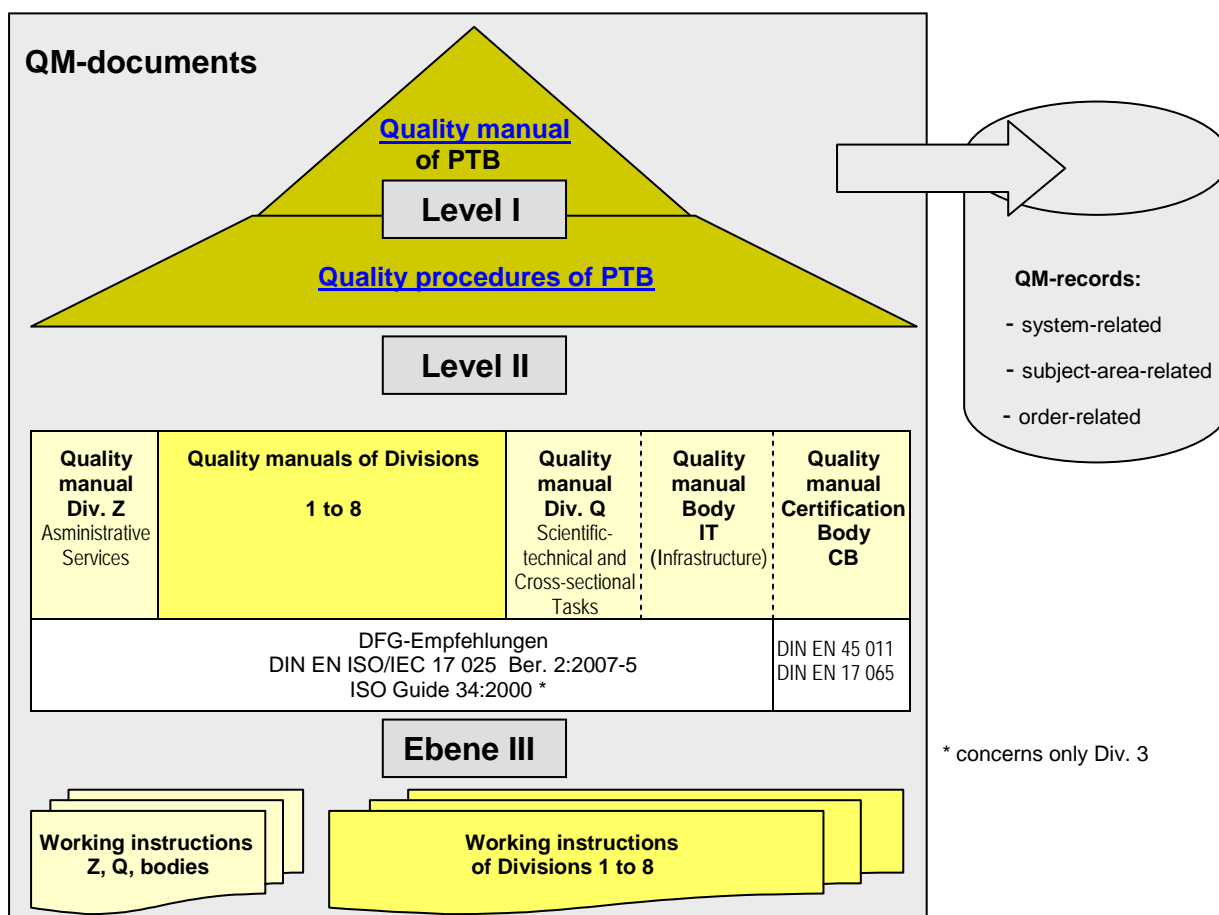


Figure 2.3.1: Quality documentation system of PTB

The **QP "Control of the quality documents"** gives further details, especially for the documents of the individual divisions, of the body "IT Infrastructure" and of the certification body.

To document the quality system's efficiency, system-, subject-area- and order-related quality records are kept.

## 2.3.4 Updating

For the superordinate types of quality documents, the following principles apply for updating:

### Quality Manual

- ⇒ Each header must indicate the type of document and the respective organizational structure.
- ⇒ The footer of the table of contents is signed by hand by the author and by the person having approved the text, including the date and the organizational status of the signing persons within PTB.
- ⇒ The approval implies a previous check by a competent third person.
- ⇒ Whenever a chapter of the quality manual is altered, the table of contents is modified accordingly. The table of contents in the quality manual is, at the same time, the list of modifications.

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# Quality manual

- ⇒ The declaration of commitment is signed by hand by the competent supreme head when the quality system is newly introduced or when fundamental modifications are being made.
- ⇒ The footers of all chapters of the quality manual contain, as information, the edition number, the author, the creation date, the contents of the chapter and the page (written in the form "page X of Y").
- ⇒ In dependence on the scope, the chapter or sub-chapter is the smallest unit of modification of the quality manual.
- ⇒ The passages whose content was amended last, and the insertions having been entered last, are marked.

## Quality procedures (QP)

- ⇒ Each header indicates the type of document.
- ⇒ The footer of the first page is signed by hand by the Senior Quality Manager of PTB, including the date.
- ⇒ The footers of all pages contain, as information, the edition number, the QP number and the page (written in the form "page X of Y").
- ⇒ The approval by the Senior Quality Manager implies a previous check by the A-QM according to the Statutes.
- ⇒ Whenever a modification is made in the QP, the latter will be completely exchanged.
- ⇒ The QP is drawn up by the WG PSt 2 "Central Quality Management".
- ⇒ The passages whose content was amended last, and the insertions having been entered last, are marked.
- ⇒ An overview of all QPs is given in PTB's Quality Manual and in the **INTRANET of PTB**.

## Working instructions (WI)

The principles for the drawing-up and approval of the working instructions are laid down in the quality manuals of the individual divisions, in the quality manual of the Certification Body and/or in the quality manual of the Body "IT Infrastructure". The respective author is responsible for the contents and the contact person for the processes described. Checking and approval are performed within the division/body, by authorized staff. Thereby, it is ensured that the amendments are checked and approved by the same body which also checked and approved the original version.

### 2.3.5 Distribution

The authorized versions of the quality manual and of the quality procedures are made accessible to every staff member of PTB. The approved originals are archived by the author. Provisions on the distribution of the working instructions are contained in the quality manuals of the individual divisions, of the certification body and of the body "IT Infrastructure". A list of the applicable working Instructions is to be found on the INTRANET on the quality management pages of the individual divisions/bodies.

A distinction is made between the following two types of copies of quality documents:

#### a) Copies which are subject to updating

The most recent authorized versions are made available on the **INTRANET of PTB**. The staff members are obliged to keep themselves informed about the latest state.

On the German **INTERNET pages of PTB**, the PTB's quality manual is published as amendment copy 01. The most recent changes will not be marked. As to the documents which are also valid, the **QP Rules for the safeguarding of good scientific practice** (without Annexes) as well as the references in the **"List of laws, ordinances and directives" (Annex 6.2 of the Quality Manual of PTB)** are made available.

The English translations of PTB's quality manual and of the **QP "Rules for the safeguarding of good scientific practice"** are available on PTB's **English Internet pages**.

#### b) Information copies which are not subject to updating

At the time of edition, these quality documents are valid but are not subject to the updating service and are not numbered. The recipients of the quality documents are registered by the staff member responsible for the distribution.

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