

3 Quality steering and control procedures

3.1 Audits

3.1.1 Internal Audits

To prove and, possibly, to enhance the effectiveness of PTB's quality management system, audits are carried out systematically in the divisions and in the Conformity Assessment Body and in the Body "IT-Infrastructure", assessing all relevant aspects of the quality management system. Furthermore, at specific occasions - such as significant changes in the quality management system or in the quality of the services - additional audits can be performed.

It is the aim of the internal audits to

- ⇒ permanently develop the quality management system with the aid of corrective and improvement actions,
- ⇒ recognize in time, and effectively rectify, deviations from the quality objectives,
- ⇒ and maintain the transparency of the quality management system for internal and external bodies (e.g. within the scope of accreditations).

In these audits it is checked whether the services provided are in agreement with the quality management requirements.

The procedure for performing an audit is described in detail in the **QP "Internal Audit"**.

External assessments of the divisions/ bodies are carried out in accordance with the specifications of external bodies and after advance information and approval by the Senior Quality Manager.

3.1.2 External assessments

In addition, PTB subjects itself to a process of international assessment through technical experts on the basis of contractual agreements. These agreements are currently the [CIPM-MRA](#), the [OIML-CS](#) and the [IECEX-System](#). This also includes in-situ assessments (on-site visits by peers) and the participation of international technical experts in internal audits and peer reviews, respectively, in the PTB.

In fields where this is required by the legislator, PTB is authorized to carry out conformity assessments and, as far as required, national accreditations. PTB is Notified Body No. 0102 according to the EU Directives 2014/32/EU (Measuring Instruments Directive), 2014/31/EU (Non-automatic weighing instruments), 2014/34/EU (ATEX Equipment Directive) and 2006/42/EC (Machinery Directive) as well as the national approving authority for the German Measures and Verification Act, the Proof Testing Act and the Weapons Law (see [Annex 6.2](#)). As contractually agreed, the assessors of the national authorizing authorities or in connection of recognition on directives 2014/31/EU and 2014/32/EU of national metrology institutes from Germany, Austria and Switzerland (D-A-CH) are granted access to all the information which is necessary for the quality management system of PTB.

In addition, the PTB is the subject of regular evaluations by the Science Council.

3.1.3 Technical supervision actions

To ensure the technical quality of the calibration and test results, PTB organizes national and international comparison measurements or takes part in such measurements. This applies, in particular, to the evidence of the metrological traceability and the comparability of the standards and standard measuring devices within the scope of the CIPM-MRA. The special entry in the database of the CIPM-MRA is regarded as an internationally recognized evidence of traceability (<http://kcdb.bipm.org/kcdb>).

Edition No.: 11	Created by: Central Quality Management	on: 2023-05-02	Chapter 3	Page of pages 1 of 3
--------------------	--	-------------------	--------------	-------------------------

3.2 Review of the quality management system

The review systems applied at PTB are included in the paper [Strategic Planning Sequences of PTB](#).

3.2.1 Self-review

Competent staff entrusted by the Presidential Board carries out a formal self-review of PTB's quality management system ("management review"). Thereby, the internal results of the reviews of the individual divisions/bodies are taken into account.

The internal audit reports, the external assessment reports and the results of comparison measurements are used to evaluate the state and the adequacy of the quality management system as regards the quality policy and the quality objectives. As a result, necessary specifications for the adjustment of the quality management system to changes due to new technologies, quality-related concepts, market requirements or the social environment are made.

The detailed procedure is specified in the [QP "Management review"](#).

3.2.2 Review through the scientific-technical community

For the further enhancement of quality in research, PTB participates in the development and operation of review systems and subjects itself in an adequate way to the review systems within the scope of the "scientific community" (see also: [Position paper of the resort research facilities "Researching-Testing-Advising"](#)).

In this context, PTB makes, in particular, use of the following possibilities:

- ⇒ Back-up of research by the Board of Consultants of PTB (advice for long-term research concepts and focal points)
- ⇒ Scientific publications in national and international journals with peer review procedures
- ⇒ Canvassing of third-party funds for research projects in competition with universities and other research institutions
- ⇒ Reviews by customer inquiries – in particular in the "services" sector
- ⇒ Evaluation by the Science Council
- ⇒ Cooperation with universities and other research institutions (formation of networks, e.g. in chemistry).

To safeguard the worldwide uniformity of the measures, PTB cooperates with other national metrology institutes at the regional European level in [EURAMET](#) and [WELMEC](#) and, at the international level, within the scope of the Meter Convention, with [OIML](#) and with the [IECEX-Systemes](#).

In addition, in October 1999, the national metrology institutes signed a multilateral agreement ([CIPM-MRA](#)) for the mutual recognition of the national standards and the respective result reports. This agreement accounts for the increasing demand for an open, transparent and comprehensive system which provides the users with reliable quantitative information regarding the comparability of the national metrological services. It establishes the technical basis for future agreements in international goods traffic and trade and is based on an intensive exchange of research results, on the disclosure of results and measuring possibilities, on comprehensive international comparison measurements and on evidence of a quality management system on the basis of EN ISO/IEC 17 025 and on the additional requirements of DIN EN ISO 17 034 for the manufacture of certified reference materials.

In this connection, the quality management system of PTB is, at regular intervals, subjected to an assessment process within the scope of EURAMET, OIML and the IECEX system, involving recognized international experts.

Edition No.: 11	Created by: Central Quality Management	on: 2023-05-02	Chapter 3	Page of pages 2 of 3
--------------------	--	-------------------	--------------	-------------------------

3.3 Dealing with risks and opportunities

Measures for error prevention are always taken jointly by the person having detected the risk of occurrence of a deviation or having recognized relevant trends, and the person responsible for the area concerned. If necessary, they are planned into account the results of risk analyses, the extent of damage in the case of error occurrence as well as probability of occurrence of the error. These measures are an essential element of the process continuous improvement of the work at PTB.

The loop of the continuous improvement processes is composed of following control stages:

- ⇒ analysis and weighting of the error risk
- ⇒ definition of measures for error prevention (risk minimization)
- ⇒ carrying-out and supervision of preventive actions (risk minimization)
- ⇒ assessment of the efficiency

Every staff member of PTB is requested to inform his superior about error risks he has recognized. Suggestions for improvement by staff members are encouraged by PTB.

The **QP "Actions to address risks and opportunities"** presents in detail the possible sources for identifying opportunities for improvement, the types of risk considered in the various fields of action and the basic procedure for handling them within PTB.

Edition No.: 11	Created by: Central Quality Management	on: 2023-05-02	Chapter 3	Page of pages 3 of 3
--------------------	--	-------------------	--------------	-------------------------