

Operation of a Quality Management System in Compliance with ISO/IEC 17025 At PTB: First Experience

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Abstract

PTB is a signatory of the CIPM Mutual Recognition Arrangement which regulates the mutual recognition of national measurement standards and of calibration and measurement certificates issued by National Metrology Institutes. Among other requirements the CIPM-MRA calls for a quality management system fulfilling the requirements of ISO Guide 25 (now replaced by ISO/IEC 17025) to assure confidence in measurements. In compliance with these requirements PTB has modified the existing quality management system in compliance with ISO/IEC 17025.

The new system is in effect since January 2001. It has been presented to the QS-forum of EUROMET on October 2001 and has been accepted by the RMO. The quality management system of PTB not only covers the services provided to external and internal users but also aims at assuring quality also in the fields of research and publication of research results.

The presentation will provide details on structure and operation of the quality management system at PTB and describe the experience that has been obtained so far.

1 INTRODUCTION

Confidence in the equivalence of work methods from organisations carrying out metrological studies also requires indirectly confidence into those calibrations carried out by national metrology institutes (NMIs). In most countries of the world these NMIs form the top of the national metrological infrastructure and provide due to their work the preconditions for a uniform metrology, if possible traceable to the SI-units. In consequence, the equivalence of the calibration and measurement results forms a substantial precondition for bilateral and multilateral conventions and agreements in most different technical fields. In addition the metrological traceability is required by several standards and laws.

In the USA, for example, “traceable to NIST“ means that there is an unbroken chain with known uncertainties traceable to the SI-units through NIST responsible for maintaining traceability to the SI for the United States [1].

In Germany the realisation of this central task is regulated by laws and was transferred to the Physikalisch-Technische Bundesanstalt (PTB) by the legislator. This mandate is directly

derived from the constitution of the Federal Republic of Germany in which the unity of metrology for the protection of citizens is explicitly requested [2].

2 MUTUAL RECOGNITION AGREEMENT BETWEEN NMI (CIPM-MRA)

The initial point for the latest development of a further consolidation of trust into the work of the NMIs is a world-wide agreement about the mutual recognition of calibration and measurement reports published by the NMIs, among the NMIs under the auspices of the METER CONVENTION. This agreement was worked out by the central working group of the METER CONVENTION, the international committee for measurement and weight (CIPM), and therefore will be called briefly in the following CIPM-MRA [3].

This CIPM-MRA was signed by 38 representatives of the NMI and by two international organisations in October 1999. The number of the signers has meanwhile risen by further nine ones so that more than 90% of the members of the meter convention have meanwhile joined this important agreement.

The reasons that have lead to this international agreement are complex. Some aspects are shown in [4, 5, 6]. It was obvious that the traditional methods practised by the NMIs were no longer sufficient.

Most important aim was to define the degree of equivalence of the national standard. This knowledge is not only important for the direct customer of the NMI but also for other NMIs, in order to be able to make funded statements about the acceptance of the measurement results of the NMI.. And with this we have come to the main aim of the mutual recognition of the metrological results published by an NMI. How these results are being called is secondary. In the PTB we call them calibration- or test certificate, test report and solely report. They all have one thing in common, they all fulfil the requirements to these profitability reports which are agreed upon in the QM-system.

How shall the equivalence of national standards be reached? Precise ways were given here. The first part seems to be well known to us metrologists. Comparing measurements. The participation in fundamental comparisons (Key Comparisons) and additional regional and national comparisons is strongly required. In order to gain confidence, the results of the comparisons including the determination of the respective measurement uncertainty have to be revealed.

As a further element, the proof of a QM-system was added. We will now deal more intensively with the role of the QMS in this agreement.

As already mentioned, the most important aim is the mutual and international recognition of metrological results. For this purpose an international database has and is being set-up in the BIPM in which the measurement and calibration capabilities of the corresponding NMIs are entered after intensive regional and international evaluation [7]. To this belongs of course, as for any serious measurement result, the indication of the measurement uncertainty. The entry into the BIPM-database is secured by a metrologically pronounced QMS which has to fully comply with the requirements of the CIPM-MRA.

In order to be competent for a certain working field, the measurement results and all that nowadays belongs to this have to be integrated into the QM-system which supplies the frame for the measurements. With this QM-system the laboratory creates confidence to get

permanent reliable measurement results, even beyond the key and supplementary comparisons. The participation in the key and supplementary comparisons are central part of this control loop. They are an important element for the competence proof and for gaining confidence

The CIPM-MRA contains two equal ways to demonstrate that the criteria of the agreement will permanently be fulfilled: Self-declaration or accreditation by an internationally accepted accreditation body [8].

For the final evaluation of the QM-system EUROMET has formed a special working group, the QS-FORUM [9]. It mainly consists of QM-experts of the NMIs. This working group evaluates the QM-system according to rules agreed upon. Basis are the documentation that has to be submitted, an oral presentation and discussion. This procedure is independent from whether the NMI has chosen the way of self-declaration or accreditation.

3 QUALITY MANAGEMENT SYSTEM OF THE PTB

The first formal Quality Manual (QMH) of the PTB was signed by the president on 1 March 1995. Basis for the QM-system was the series of European standards EN 45 000. The efforts to emphasize the technical competence for metrological services of the PTB and to make them transparent to third parties were ostensible.

Furthermore, this QM-system included special working fields where the German legislator demands accreditation according to European standards (eye protection, EMV, explosion protection, ear protection, medical devices). Of course the QM-system of the accreditation body of the DKD is part of this.

At the end of the 90s, a new decisive era began for the advancement of PTB's QM-system. Actuators were the looming new formulation of the ISO Guide 25, the signature of the CIPM-MRA and the more and more complex getting customers' requests for a measurement traceability.

In addition, fundamental rules for protection of a good and approved scientific working procedure were requested.

The adaptation and advancement of our QMS, which was originally aligned to the services of the PTB, to the extended requirements of the ISO/IEC 17025 were now part of the agenda.

As already mentioned, the continuous advancement of PTB's QM-system got strong impulses by the development of the international standard ISO/IEC 17025 in the year 1999 [9]. That's why the QM-documentation system of the PTB was adapted according to the requirements of this standard. In compliance with the superior rules, like terms of reference and rules of procedure of the PTB, the department "quality management" has developed the PTB-wide valid QM-principles and QM-structures and reconciled them with the presidential board and documented them in the new Quality Manual of the PTB.

Thereby the special QM-requirements of the German research community (DFG) [10] were additionally integrated into the advanced QM-system of the PTB.

At the same time aspects of a process-oriented organisation of the PTB were taken into consideration for the advancement of the QM-system.

This QM-system which has been modified within the last two years and which fully complies with the criteria of the CIPM-MRA, is used since January 2001. It was introduced to the QS-forum on October 2001 and confirmed by the QS-forum after extensive testing and discussion.

3.1 Quality organisation of the PTB

Figure 1 shows the QM-organisation of the PTB. It is structured quite simple. On top is the president. He lays down the principles and decides finally. He is independent and free in his statutory decisions.

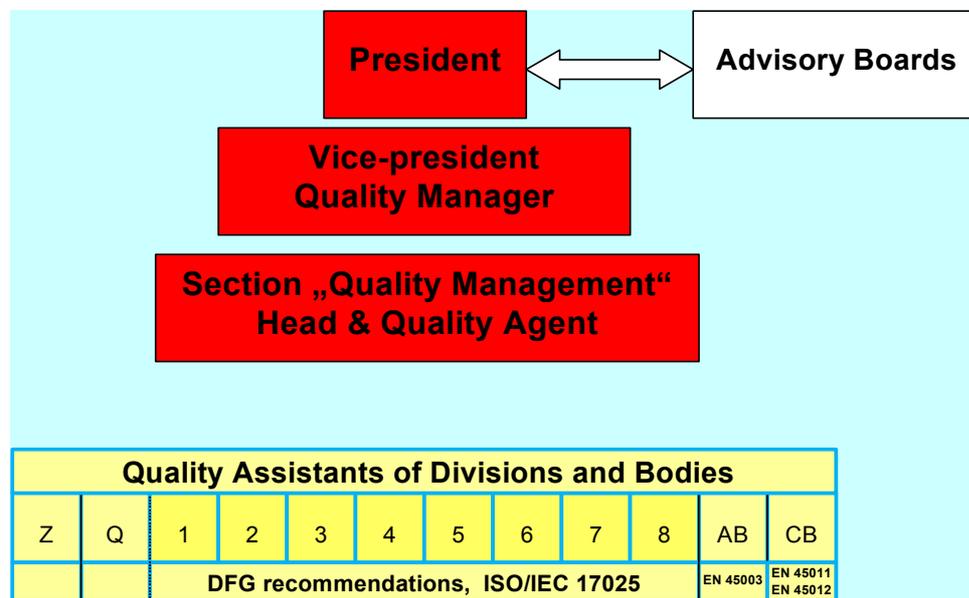


Figure 1: Quality organisation of the PTB

In the more strict sense the QM-organisation is structured in two levels.

The **first level** is formed by the Quality Manager and by the Quality Agent. They are members themselves or do have direct access to the upper management of the PTB. The Vice President of the PTB is the quality manager. He represents the concerns of the QM-system within the presidential board of the PTB. The presidential board of the PTB is advised by different advisory boards. The department "Quality Management" is responsible for the construction, the maintenance and the coordination of the QM-system of the whole PTB and he is technically directly under the quality manager. The manager of this department is the QM-representative of the PTB.

The **second level** is formed by the QM-Assistants of the divisions and bodies. They support the section "Quality Management" and are responsible for the construction and maintenance of the QM-system of their divisions or bodies.

3.2 QM-Projects

In order to integrate the ideas and initiations of many co-workers into the advancement of the QM-system, special QM-projects were arranged in all departments of the PTB. The work of these project was generally limited in time to two years.

After conclusion of this structure phase, the tasks of the Quality Assistants were taken over. Their main task is the support of the department management in all concerns of the quality management. They are competent contact person and expert for QM in their department.

3.3 QM-Documentation

Figure 2 gives an overview on the QM-documentation of the PTB. It is three-stage constructed.

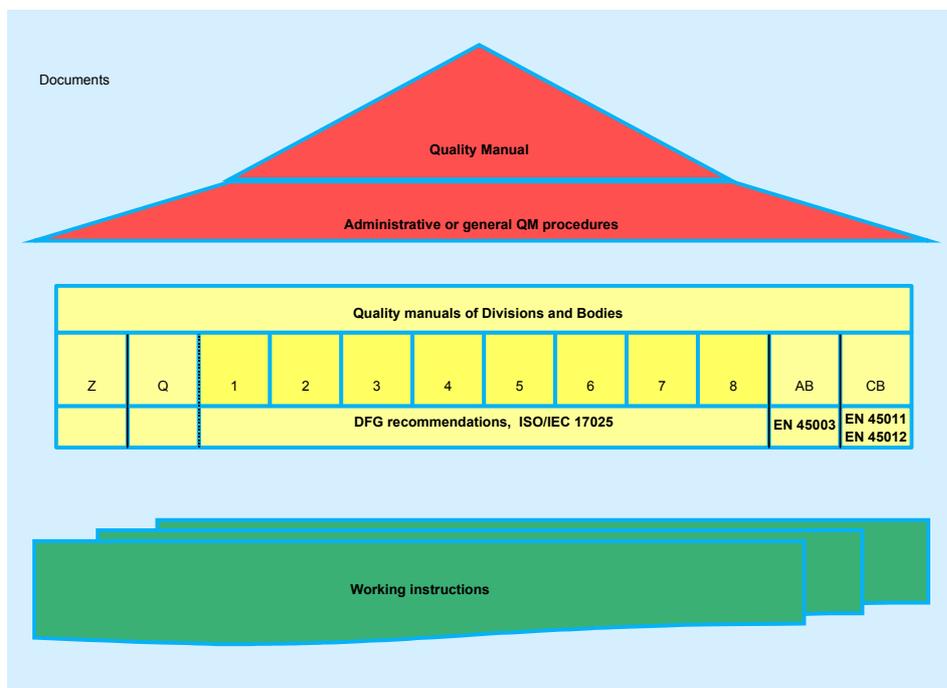


Figure 2: QM-Documentation of the PTB

Level I

At the top of the documentation pyramid is the Quality Manual (QMH) and the administrative and general procedures for quality management (QM-VA) of the PTB. The QM-VA are supplemented instructions of the PTB's Quality Manual.

Level II

In Level II are the QMH of the technical departments of the PTB. The predefinitions of the QMH and the QM-VA of the PTB are detailed in these area-specific QMH for activities of

the departments in the sense of the DFG-recommendations for a good scientific practice as well as the requirements of the ISO/IEC 17025.

The QM-documents of Level II specify the textual, structural and formal requirements to the activity-specific work instructions.

Level III

The activity-specific work instructions of the departments form the basis of the documentation pyramid in the QM-system. These are above all the measuring station descriptions, calibration and test instructions, instructions (if required) from R&D, general service/administration.

3.3 QM and covered calibration and measurement capabilities

The PTB has contributed more than 1000 entries to the calibration and measurement capabilities database of the BIPM. These entries relate to the following areas of activities:

- acoustics, ultrasound, vibration
- electricity and magnetism
- length
- mass and related quantities
- photometry and radiometry
- amount of substances
- ionizing radiation
- thermometry
- time and frequency

The calibration and measurement capabilities can be looked up in the Internet under <http://kcdb.bipm.fr/BIPM-KCDB/AppendixC>, directly from the BIPM database. This list is a part from the spectrum of services of the PTB, which are covered by the QM-system. All entries in the database are completely covered by the QM-system.

4 FIRST EXPERIENCE

The principle item of the QM-system in terms of the CIPM-MRA are the eight technical departments of the PTB [11]. The other departments and bodies are also integrated into the QM-system, however they are of subordinate interest for the agreement.

We all knew that the advancement of the QM-system would require additional work and efforts, at least during the initial phase, especially for the compilation of the necessary documentation. But during the precise formulation we found out that in many cases the work had already been done.

Documented fundamentals already partly existed in the laboratories. They only had to be supplemented, bundled and sorted according to QM-aspects.

Today we are happy that we have taken these external incitements as an occasion to reconsider our philosophy with respect to quality assurance and quality management and to

set new key aspects for the advancement of the QMS. The fundamental decision for orientation of PTB's QM-system at the ISO/IEC 17025 has proven itself. Here we have to point out that during practical realisation we have managed to involve almost all co-workers and to integrate their ideas and visions. An open system was realised that takes all metrological fields of activities into consideration and simply allows an extension to new activities. A simple organisation and documentation system was realised which meets our co-workers' needs and at the same time corresponds to the requirements of the CIPM-MRA.

Management and control processes have proven to be important and helpful elements which are defined in PTB's QM-system. They are helpful to keep us on the right track. Reliable indicators are our mechanisms for critical self-evaluation of our own work like e.g. improvement programs, internal audits and management evaluations.

Since 1997 management reviews are regularly carried out within PTB. The president of the PTB and the department managers are responsible for the transaction of the management reviews. The management reviews is the highest management and control process within PTB's QM-system.

The internal audits play another important role. They are an important input parameter for the management evaluation. Since 1995 planned audits are carried out within the PTB. During these audits all relevant aspects of the QM-system are surveyed. Most important aim of the internal audits is to continuously advance the QM-system with the help of carried out correction and improvement measures and to realise and remove effectively deviations from the quality targets on time.

Here, not the control but the aimed improvement is centred. For this purpose, suitable and highly motivated auditors are required. They have to act as internal advisors, pick up signals and stimulate a continuous improvement process. In order to support this activity, extensive education and training seminars were carried out for the internal auditors within the past two years. Keeping upright the high qualification level of the internal auditors is very important for us. Their work is of immense significance for the acceptance of the QM-system and for the motivation of all co-workers to contribute to the further development of the QM-system.

5 SUMMARY

The PTB is signer of the CIPM-MRA for mutual recognition of the national standard and of the corresponding profitability reports. Basis are international and regional comparison measurements as well as the establishment of a QM-system on the basis of the ISO/IEC 17025

The signatories have undertaken to set up and operate a quality system at their institutes. For the implementation of this arrangement, EUROMET has founded a QS-Forum in which the EUROMET members present their QM-system.

In this connection, representatives of the PTB successfully presented their QM-system. The documents submitted served to prove that the calibration and measuring capabilities stated are fully covered by the quality management system and meets the EUROMET requirements.

REFERENCES

- [1] Traceability – NIST Policy and Supplementary Materials (www.nist.gov/traceability)
- [2] Charter of the Physikalisch-Technischen Bundesanstalt (PTB) (www.ptb.de/en/satzung/satzungs_e.pdf)
- [3] CIPM-MRA, Mutual recognition of national measurement standards and of calibration and measurement certificates issued by national metrology institutes, Paris, 14 October 1999
- [4] W.R. Blevin: National and international needs relating to metrology, appropriate international collaborations, and the role of the BIPM, 1998
- [5] K. Birkeland: Legal Metrology at the Dawn of the 21st Century. 33rd CIML Meeting, Seoul, 10/1998
- [6] H. Kunzmann; A. Odin: Third Party or self declaration. NCSL conference 2000, Toronto
- [7] EUROMET-Documents, Guide 8 "Review Criteria and Procedure for EUROMET CMC" (www.euromet.ch)
- [8] ILAC Mutual Recognition Arrangement, signed in Washington, November 2000 (www.ilac.org)
- [9] EUROMET QS-FORUM (www.initiation.nl)
- [10] EN ISO/IEC 17025: 2000 General requirements for the competence of testing and calibration laboratories
- [11] Empfehlungen der Kommission "Selbstkontrolle in der Wissenschaft" der Deutschen Forschungsgemeinschaft (DFG): Grundsätze zur Sicherung guter wissenschaftlicher Praxis, Januar 1998 (www.dfg.de/foerder/gute_praxis.html)
- [12] PTB Annual Report 2001, Braunschweig, 2002 (ISSN 0340-4366)