Criteria and procedures for the approval of the quality systems of measuring instruments manufacturers

according to

- the German Measures and Verification Ordinance (MessEV), Annex 4, module D or D1
- the European Measuring Instruments Directive (2004/22/EC, MID), Annex D, D1 or H1
- the European Measuring Instruments Directive (2014/32/EU, MID), module D or D1
- the European Directive on nonautomatic Weighing Instruments (2004/22/EU, NAWID), module D or D1

by 01/2016
Structure

- Introduction
- Comparison ISO 9001-certification / QS-approval
- Procedure QS-approval
- Contact
New German Measuring and Verification Law (since 2015)

**Former law (EichG)**

- PTB
  - Type approval
- Verification authority
  - Initial verification

**New law (MessEG)**

- Manufacturer + CAB
  - Conformity assessment
- Manufacturer
  - Conformity declaration
- Verification authority
  - Market surveillance
- Verification authority
  - Verification
    - User surveillance
Roll-out of new measuring instruments

Typical procedure at a manufacturer

1. Market research
   - Concept, Customer requirement specifications

2. Development Construction
   - Product requirement specifications, Design, Techn. Documentation, Prototype

3. Development Verification
   - Specimens, Type tests, Design-validation

4. Process planning
   - Manufacturing instructions, Production facilities, Meas. and test equipment

5. Production
   - Components, Final products, Final inspection

6. Distribution
   - Start-up, service, maintenance
Former legal inspections

Old German verification law

- Market research
- Development
- Concept, Customer requirement specifications
- Product requirement specifications, Design, Techn. Documentation, Prototype

- Development
- Verification
- Specimens, Type tests, Design-validation

- Process planning
- Manufacturing instructions, Production facilities, Meas. and test equipment Contracts with suppliers

- Production
- Components, Final products, Final inspection

- Supplier
- Purchase

- Distribution, Start-up, service, maintenance

Type approval

Initial verification

10.49
98.03

D 86
6.131.96
Conformity assessment procedures (modules) according to the German MessEV annex 4

possible:
For all kinds of instruments:  B+D, B+F
Further modules for specific kinds of instruments
See: www.rea.ptb.de

PTB-Offer:
Modules B, D, D1, G
Conformity assessment procedures (modules) according to directive 2004/22/EC (MID) until 19/04/2016

- **MI-001**, Water meters:
- **MI-002**, Gas meters and volume conversion devices
- **MI-003**, Active electrical energy meters
- **MI-004**, Heat meters
- **MI-005**, Measuring systems for the continuous and dynamic measurement of quantities of liquids other than water
- **MI-006**, Automatic weighing instruments
- **MI-007**, Taximeters
- **MI-008**, Material measures
- **MI-009**, Dimensional measuring instruments
- **MI-010**, Exhaust gas analysers

- Technical documentation of the manufacturer
Conformity assessment procedures (modules) according to directive 2014/32/EU (MID) starting 20/04/2016

<table>
<thead>
<tr>
<th>Mod. A</th>
<th>Internal production control</th>
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<tbody>
<tr>
<td>Mod. A2</td>
<td>Internal production control + product testing</td>
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<tr>
<td>Mod. B</td>
<td>Type examination</td>
</tr>
<tr>
<td>Mod. C</td>
<td>Internal production control</td>
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<tr>
<td>Mod. C1</td>
<td>Internal production control + product testing</td>
</tr>
<tr>
<td>Mod. D</td>
<td>Assessment + surveillance of QS production</td>
</tr>
<tr>
<td>Mod. D1</td>
<td>Assessment + surveillance of QS production</td>
</tr>
<tr>
<td>Mod. E</td>
<td>Assessment and surveillance of QS product</td>
</tr>
<tr>
<td>Mod. E1</td>
<td>Assessment and surveillance of QS product (if so, statistic. verific.)</td>
</tr>
<tr>
<td>Mod. F</td>
<td>Product verification</td>
</tr>
<tr>
<td>Mod. F1</td>
<td>Product verification (if so, statistic. verific.)</td>
</tr>
<tr>
<td>Mod. G</td>
<td>Unit verification</td>
</tr>
<tr>
<td>Mod. H</td>
<td>Assessment and surveillance of full Quality Assurance</td>
</tr>
<tr>
<td>Mod. H1</td>
<td>Assessment and surveillance of full Quality Assurance + Design examination</td>
</tr>
</tbody>
</table>

| Technical documentation of the manufacturer |

• MI-001, Water meters: B+D, B+F, H1
• MI-002, Gas meters and volume conversion devices: B+D, B+F, H1
• MI-003, Active electrical energy meters: B+D, B+F, H1
• MI-004, Heat meters: B+D, B+F, H1
• MI-005, Measuring systems for the continuous and dynamic measurement of quantities of liquids other than water: B+D, B+F, G, H1
• MI-006, Automatic weighing instruments: B+D, B+E, B+F, D1, F1, G, H1
• MI-007, Taximeters: B+D, B+E, B+F, G, H1
• MI-008, Material measures: B+D, B+E, B+F, D1, F1, G, H1
• MI-009, Dimensional measuring instruments: B+D, B+E, B+F, D1, E1, F1, G, H1
• MI-010, Exhaust gas analysers: B+D, B+E, B+F, D1, E1, F1, G, H1

PTB-Offer: Modules B, D, D1, G

Physikalisch-Technische Bundesanstalt ■ Braunschweig und Berlin
Conformity assessment procedures (modules) according to directive 2014/31/EU (NAWID)

starting 20/04/2016

Technical documentation of the manufacturer

- Mod. B
  Type examination

- Mod. D
  Assessment + surveillance of QS production

- Mod. F
  Product verification (if so, statistic. verific.)

- Mod. D1
  Assessment + surveillance of QS production

- Mod. F1
  Product verification (if so, statistic. verific.)

- Mod. G
  Unit verification

Possible:

- Nonautomatic weighing instruments:
  - B+D, B+F, G

- Nonautomatic weighing instruments, which do not use electronic devices and the load-measuring device of which does not use a spring to balance the load:
  - B+D, B+F, D1, F1, G

- If the instrument’s performance is sensitive to gravity variations, the conformity assessment according to module D, D1, F, F1 or G may be carried out in two stages, with the second stage carried out at the place of use of the instrument.

PTB-Offer:
- Modules B, D, D1, G
Detailed description of the modules

German Measures and Verification Ordinance (MessEV):
See annex 4:
- Part 1 „General provisions“
- Part 2 „Details of conformity assessment procedures“

See annexes A-H1

European Measuring Instruments Directive 2014/32/EU (MID):
See annex II

European Directive on Nonautomatic Weighing Instruments 2014/31/EU (NAWID):
See annex II
Module combination B+F

Modules B+F: Type examination (B) + Product verification (F)

Applicable for small batch production
(Comparable to former type approval and verification)
Module combination B+D

Modules B+D: Type examination (B) + QS-approval (D)

Applicable for large batch production with an existing ISO 9001 certificate
Requirements to the quality system

Extract from German MessEV Annex 4, Part 2, Module D:

3.2. The quality assurance system must be so structured that the **compliance of the measuring instrument with the type described in the type examination certificate and the relevant requirements of the Weights and Measures Act and this Regulation is ensured.**

3.3. All the elements, requirements and provisions adopted by the manufacturer must be **documented in a systematic and orderly manner in the form of written principles, procedures and instructions.** This quality system documentation must be designed in such a manner as to ensure consistent interpretation of the **quality programmes, plans, manuals and records.** It must contain in particular an adequate description of the following:

3.3.1. The **quality objectives and organisational structure, responsibilities and powers of the management with regard to product quality,**

3.3.2. the corresponding **manufacturing, quality control and quality assurance techniques, processes and systematic measures** that will be implemented,

3.3.3. the **examinations and tests** that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,

3.3.4. **quality records** such as inspection reports, test data, calibration data and qualification reports on the personnel involved and other reports required to assess the quality assurance system and

3.3.5. the means of **monitoring the achievement of the required product quality and the effective operation of the quality assurance system.**
Module D1

Modules D1: QS-approval production (D1) - c.f. D without B
• Introduction

• Comparison ISO 9001-certification / QS-approval

• Procedure QS-approval

• Contact
## Comparison ISO 9001-Certificate / QM-Approval

<table>
<thead>
<tr>
<th>Purpose of Quality-System</th>
<th>ISO 9001-Certification</th>
<th>QS-Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Compliance with customer requirements</td>
<td>Securing of the compliance of measuring instruments with legal requirements</td>
</tr>
<tr>
<td></td>
<td>Decrease of failure costs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Continuous improvement</td>
<td></td>
</tr>
</tbody>
</table>

| Purpose of certificate     | Get customer confidence | Authorisation of conformity declaration |

| Scope of certificate       | All processes and products of an organisation | Measures of quality assurance for certain product categories (includes if necessary further organisations – i.E. subcontractors) |

| Typical procedure          | Application / audit / evaluation / decision / surveillance | Application / audit / evaluation / decision / surveillance |

| Validity period            | 3 years | 3 years |

| Surveillance period        | Annual surveillance visits | Annual surveillance visits + unexpected visits |
Effect of an existing ISO 9001-Certificate for QS Approval

- An ISO 9001-Certificate does not replace the approval audit by the CAB
- ISO 9001-Certification is not a requirement for the approval of the quality system, but helpful (lower costs, audit of notified body is restricted to the „technical delta“)
- Some bodies offer ISO 9001-Certification in addition to the approval of the quality system (not PTB)

Useful WELMEC-Guide for Measuring Instrument Manufacturers:
Presumption of Conformity of the Quality System of Manufacturers with Module D or H 1 when EN ISO 9001:2000 is applied“
http://www.welmec.org/latest/guides/86.html
Structure

• Introduction
• Comparison ISO 9001-certification / QS-approval
• Procedure QS-approval
• Contact
Procedure of the QS-Approval

1. Provision of information
2. Application
3. Order confirmation
4. Nomination of the audit team
5. Stage 1 Audit
   - Evaluation of the quality system
   - Decision about QM-Approval
   - Updating the certificates database
   - Evaluation of notifications on changes of the quality system
   - Annual surveillance visits + spot check, where appropriate
   - Reassessment (after 3 years)

Supplementary:
- www.kzs.ptb.de
- Application form
- AGB + AZB of PTB
- Action plan
- Audit report
- Evaluation report
- Certificate
- Database MICert
- Certificate Revision
- Audit report
- Certificate Revision
Application documents which have to be submitted

- Filled and signed application form + list of preliminary questions
- Acceptation of the General Terms and Conditions of Certification of the PTB
- Copies of existing QM-Certificates, audit-reports etc. relevant to the QS-approval (e.g. ISO 9001 certificates, accreditation certificates)
- List of the measuring instrument types which are designated for the Conformity Declaration with regard to the quality system approval applied
- Copies of type-examination-certificates (unless not issued by PTB)
- Quality plans for several measuring instrument types, (i.e. short description of the key elements of production to make sure that the requirements of the MID will be met, e.g. quality system approval of suppliers, 100% final inspection including calibration, justification and sealing or placing into operation on site by own service technicians)
- Quality Management Manual of the company
- List of all documents subordinated to the QMM and relevant to the quality system approval

All documents have to be submitted in German or English !!!

Further documents will be requested by the audit team during the approval procedure
### QS-Approval Certificate

**Purpose:** This certificate certifies the approval of a quality assurance system.

**Certificate Details:**
- **Certificate No.:** DE-MQA-PTB<XX>, Revision <XX>
- **Date:** <TT.MM.JJJJ>
- **Issuing Body:** PTB

<table>
<thead>
<tr>
<th>Ausgabe</th>
<th>Datum</th>
<th>Änderungen</th>
</tr>
</thead>
<tbody>
<tr>
<td>DE-MQA-PTB&lt;XX&gt;, Revision 00</td>
<td>&lt;TT.MM.JJJJ&gt;</td>
<td>&lt; &gt;</td>
</tr>
<tr>
<td>DE-MQA-PTB&lt;XX&gt;, Revision 01</td>
<td>&lt;TT.MM.JJJJ&gt;</td>
<td>&lt; &gt;</td>
</tr>
</tbody>
</table>

The certificate includes a section on the history of the certificate, detailing revisions and changes. It is marked with the current date: 21.03.2023.

**Preliminary Remarks:**

**Conformity Assessment Body (CAB):**
- PTB (Physikalisch-Technische Bundesanstalt)

**Signatory:**
- [Signature]

**Reference No.:** PTB-032-<XXXXXXX>

**Certificate holder:**
- Braunschweig, <TT.MM.JJJJ>

**Certificate holder's address:**
- PTB, 32-<XX> Braunschweig, Germany

**Certificate issue date:**
- 21.03.2023

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**Additional Notes:**
- The certificate is designed to ensure the quality and reliability of the measuring instruments.
- It is essential for the continued operation and maintenance of the quality assurance system.

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**Company Information:**
- Physikalisch-Technische Bundesanstalt
- Braunschweig und Berlin

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**Quality Assurance System:** The certificate is issued by PTB, ensuring that the quality assurance system meets the required standards.
<table>
<thead>
<tr>
<th>Location 1</th>
<th>Location 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equipment:</td>
<td>Equipment:</td>
</tr>
<tr>
<td>Kind of measuring instruments:</td>
<td>Kind of measuring instruments:</td>
</tr>
<tr>
<td>Measuring:</td>
<td>Measuring:</td>
</tr>
<tr>
<td>Instrument:</td>
<td>Instrument:</td>
</tr>
</tbody>
</table>

The conformity assessment body maintains a list of measuring instrument types covered by this certificate.
List of measuring instrument types

Physikalisch-Technische Bundesanstalt
Braunschweig und Berlin
Konformitätsbewertungsstelle/Conformity Assessment Body

Liste der vom anerkannten QS-System abgedeckten Messgerätetypen
List of the measurement instrument types covered by the approved QS system

Hersteller/Manufacturer: <Hersteller>  RegNr: <DE-M-AQ-PTBXXX>

1. Messgeräte, für die der o.g. Hersteller die Konformität erklärt:
Measuring instruments for which the above-mentioned manufacturer declares conformity:

<table>
<thead>
<tr>
<th>Typbezeichnung</th>
<th>Geräteart</th>
<th>Nr. der BPB*/Bauartzulassung**</th>
<th>Fertigungsstandort</th>
<th>Bemerkungen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type designation</td>
<td>Device type</td>
<td>No. of TEC* / Type approval**</td>
<td>Production site</td>
<td>Remarks</td>
</tr>
</tbody>
</table>

2. Messgeräte, die an Kunden geliefert werden, die selbst die Konformität erklären:
Measuring instruments which are supplied to customers who declare conformity themselves:

<table>
<thead>
<tr>
<th>Typbezeichnung</th>
<th>Geräteart</th>
<th>Nr. der BPB* / Bauartzulassung**</th>
<th>Fertigungsstandort</th>
<th>Kunde</th>
<th>Bemerkungen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type designation</td>
<td>Device type</td>
<td>No. of TEC* / Type approval**</td>
<td>Production site</td>
<td>Customer</td>
<td>Remarks</td>
</tr>
</tbody>
</table>

* Baumusterprüfbescheinigung (BPB)  ** Innerstaatliche Bauartzulassung im Rahmen der Übergangsregelung nach § 62 (2) MessEG
* Type-examination Certificate (TEC)  ** National Type Approval within the framework of the transitional provision according to Section 62 (2) MessEG

Änderungen sind mitteilungspflichtig/Any changes have to be advised to PTB.

Braunschweig, <Datum>  Im Auftrag On behalf of PTB  Siegel Seal
Audit-team for quality system assessment

Audit-team has to provide as follows:

- Well-founded knowledge on legal metrology
- Knowledge in quality management (auditor training)
- Expertise in corresponding measuring instruments category

Typical audit team:

- Lead-Auditor
- Technical Expert

Both registered in the list of auditors of PTB
The conformity assessment body of PTB is equipped with competent auditors and experts from the German verification authorities, from the technical PTB divisions and from other CABs.
Estimated charges (non-binding experience values)

Computation of fees according to effort and the work performed
- Basis: Regulations Governing the Charges for Services Supplied by PTB
- ca. 1.100 € /day /person * plus travel expenses (* will be increased soon)

Effort depends on
- Scope of the measuring instruments category
- Complexity of development-/ manufacturing process
- Number of locations and potential contractual partners to be taking into account
- Potential additional labour (i.e. translations, additional audits)

Typical effort for the initial approval
(Module D, 1 instrument category, 1 location, German language, ISO 9001-Certificate present)
- Stage 1 Audit:
  Lead Auditor: ½-1 day on location + travel time, ½ day pre-/post processing
- Stage 2 Audit:
  Lead Auditor: 1-2 days on location + travel time, 1-2 days pre-/post processing
  1 Expert: 1-2 days on location + travel time, 1-2 days pre-/post processing
- Certification Body: 1 day
Changes on an approved QM-System to be notified

Examples for notifiable Changes:

- Relocation or extension of sites
- Change of a subcontractor for metrological relevant components
- Change of testing methods in final inspection of the production
- Basic changes in production process
- Lapse of ISO 9001-Certification
- Add new measuring instrument types on the scope of quality system approval

-> notification to audit team
-> review by the notified body
-> potential changes of QM-Approval
Structure

- Introduction
- Comparison ISO 9001-certification / QS-approval
- Procedure QS-approval
- Contact
Contact experts (modules B or G)

Technical questions concerning modules B or G:

Length and area measuring instruments
- Ingo Lohse
  Tel. +49 531/592-5340
Measuring instruments for liquids
- Michael Rinker
  Tel. +49 531/592-1380
Measuring instruments for gas
- Rainer Kramer
  Tel. +49 531/592-1330
Measuring instruments for thermal energy
- Jürgen Rose
  Tel. +49 30/3481-7250
Measuring instruments for electrical energy
- Manfred Kahmann
  Tel. +49 531/592-2300
Weighing Instruments
- Oliver Mack
  Tel. +49 531/592-1143
Measuring instruments of the grading of cereals and oilseeds
- Regina Klüß
  Tel. +49 531/592-3337
Densitymeters and contentmeters
- Henning Wolf
  Tel. +49 531/592-3320
Measuring instruments for temperature
- Steffen Rudtsch
  Tel. +49 30/3481-7650
Pressure gauges
- Wladimir Sabuga
  Tel. +49 531/592-3230
Measuring Instruments for traffic control
- Frank Märtens
  Tel. +49 531/592-1633
Exhaust gas analysers
- Arne Kuntze
  Tel. +49 531/592-3207
Measuring devices for diary examinations
- Regina Klüß
  Tel. +49 531/592-3337
Taximeters
- Helga Grohne
  Tel. +49 531/592-1632
Soundlevelmeters
- Ingolf Bork
  Tel. +49 531/592-1531
Measuring Instruments for Radiation Protection
- Oliver Hupe
  Tel. +49 531/592-6310
Software in Measuring Instruments
- Ulrich Grottker
  Tel. +49 531/592-2020

General questions concerning modules B or G:

Non Automatic Weighing Instruments
- Dorothea Knopf
  Tel. +49 531/592-1100
OIML-Certifications
- Dorothea Knopf
  Tel. +49 531/592-1100
Measuring Instruments Directive
- Harry Stolz
  Tel. +49 531/592-8320
Domestic and EEC-Type Approvals
- Barbara Wegner
  Tel. +49 531/592-8313
Contact experts (modules D or D1)

PTB working group Q.32:

Markus Urner,
Coordinator QS-approval measuring instrument manufacturers
Tel. +49 531/592-8321, E-Mail: markus.urner@ptb.de

Anna Pfaff,
Coordinator QS-approval weighing instrument manufacturers
Tel. +49 531/592-8322, E-Mail: anna.pfaff@ptb.de

General questions

General questions on legal metrology in Germany:
PTB Working Group Legal Metrology (Q.31)
Dr. Mäuselein sascha.maeuselein@ptb.de

General questions on conformity assessment services of PTB:
Office PTB-CAB (Q.32)
Dr. Stolz harry.stolz@ptb.de

Other CABs:
Domestic:
http://www.adkbs.ptb.de/
European:
http://ec.europa.eu/enterprise/newapproach/nando/