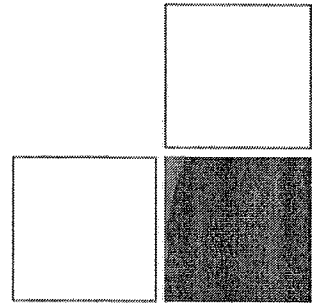


Criteria and procedures for the approval of the quality systems of measuring instruments manufacturers

according to

- the German Measures and Verification Ordinance (MessEV), Annex 4, module D or D1
- the European Measuring Instruments Directive (2014/32/EU, MID), module D or D1
- the European Directive on nonautomatic Weighing Instruments (2014/31/EU, NAWID), module D or D1

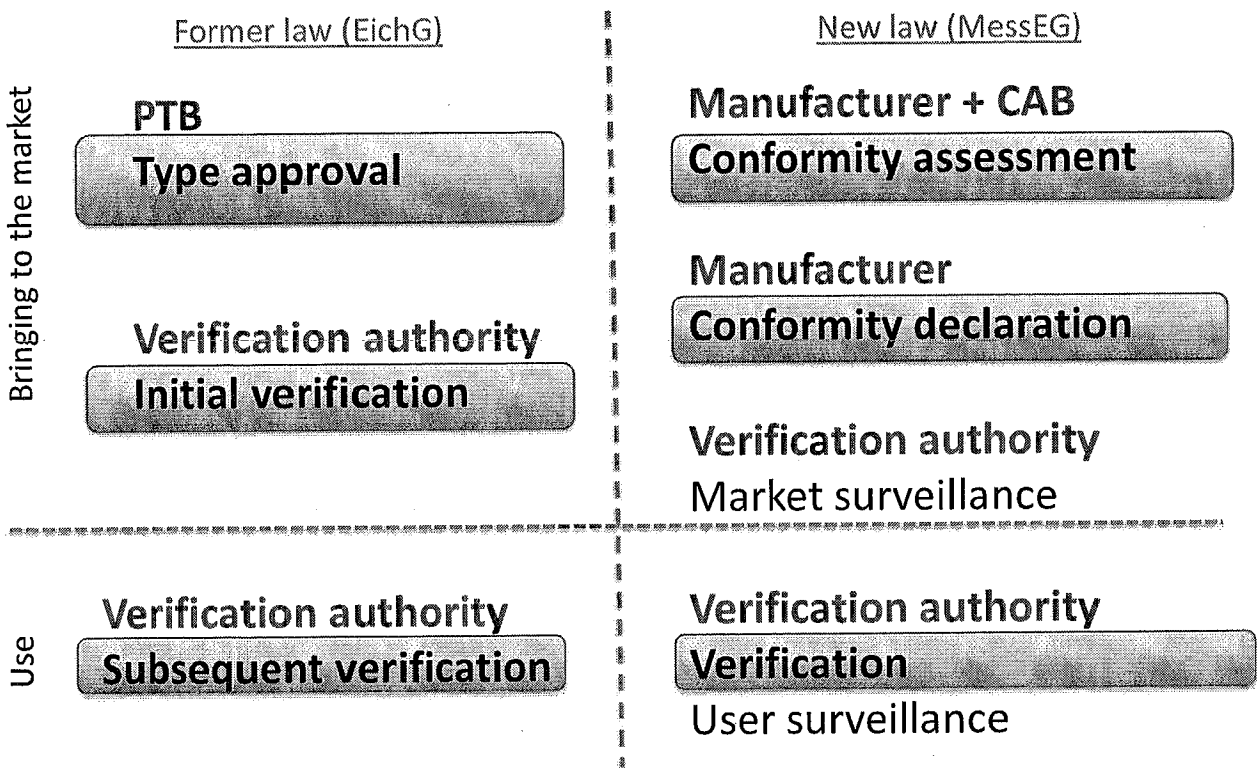
by 08/2018



Structure

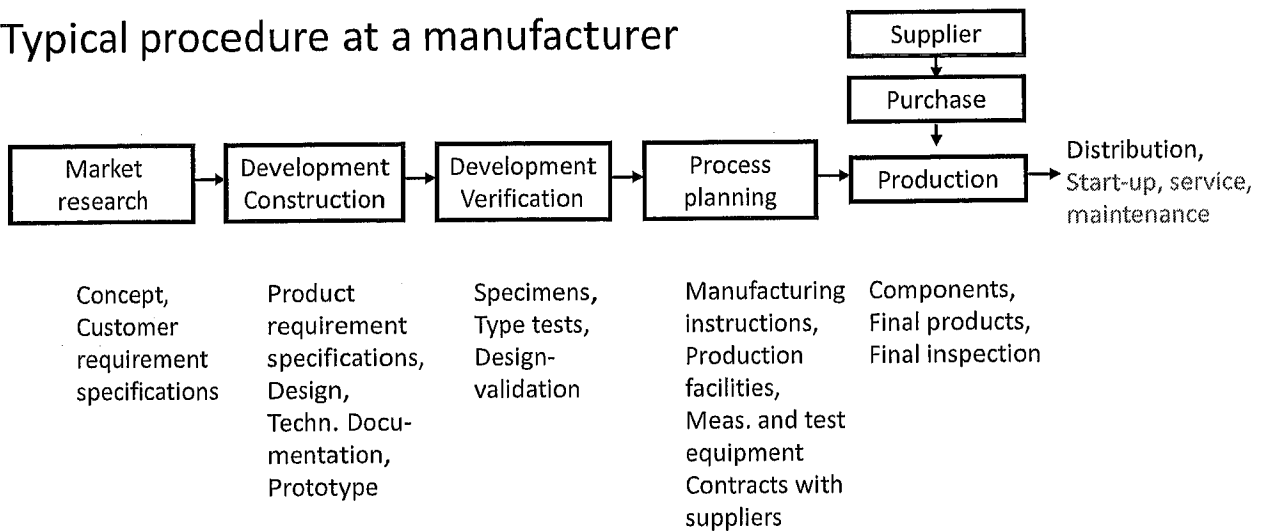


- Introduction
- Comparison ISO 9001-certification / QS-approval
- Procedure QS-approval
- Contact



Roll-out of new measuring instruments

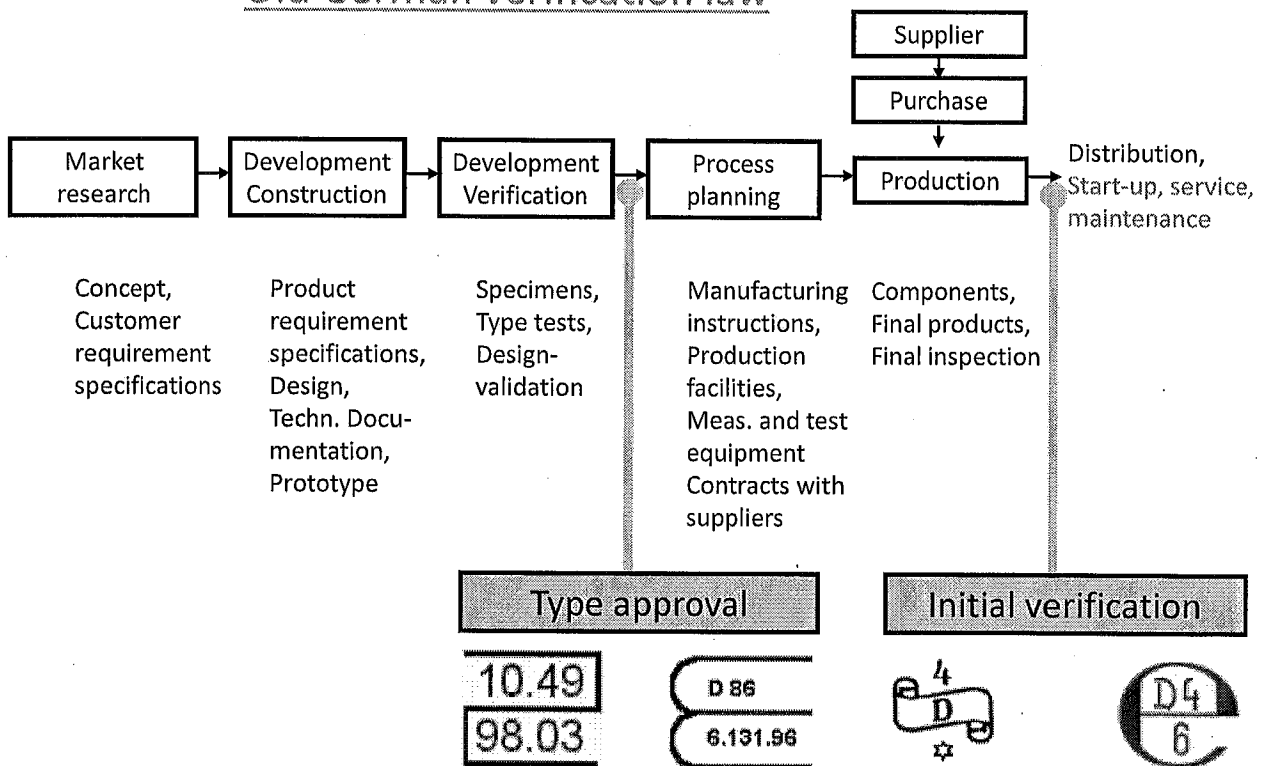
Typical procedure at a manufacturer



Former legal inspections



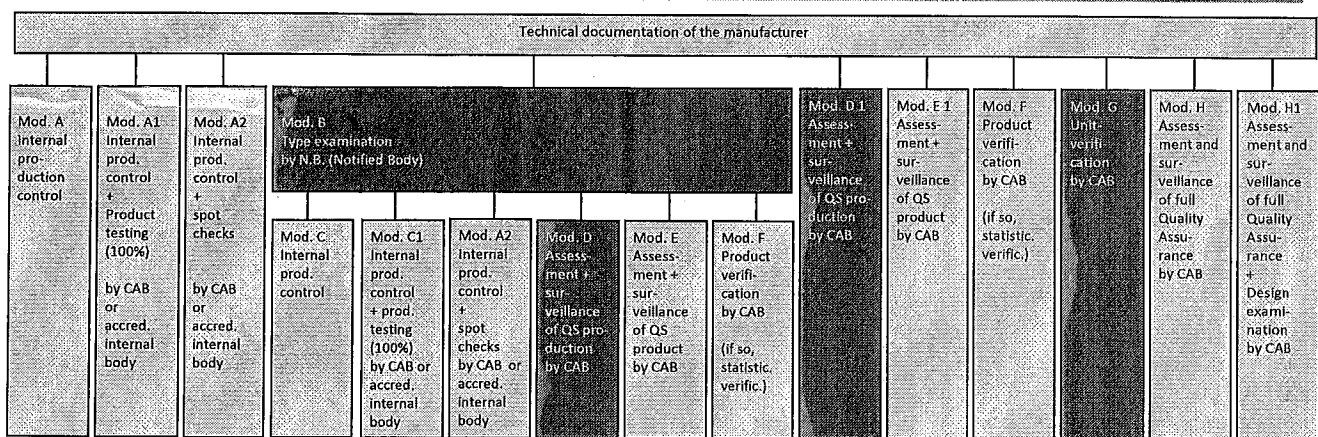
Old German verification law



Physikalisch-Technische Bundesanstalt ■ Braunschweig und Berlin

Page 5

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



possible:

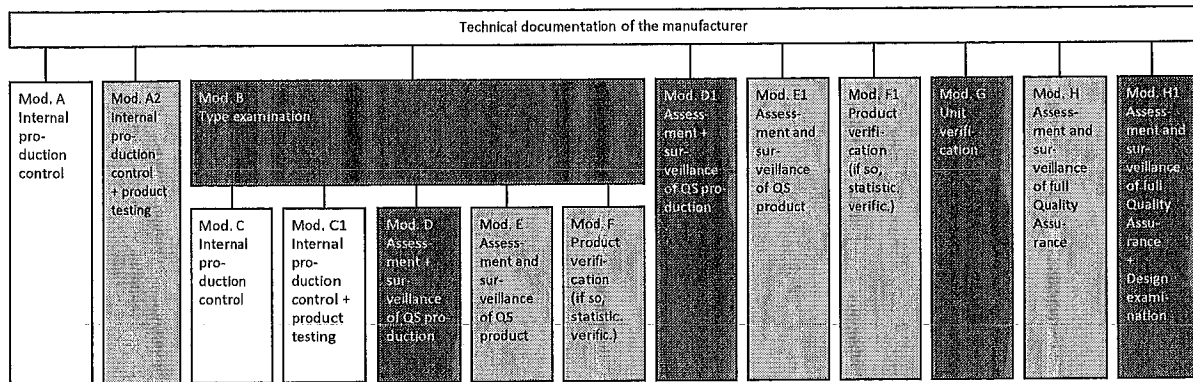
For all kinds of instruments: B+D, B+F

Further modules for specific kinds of instruments

See: www.rea.ptb.de



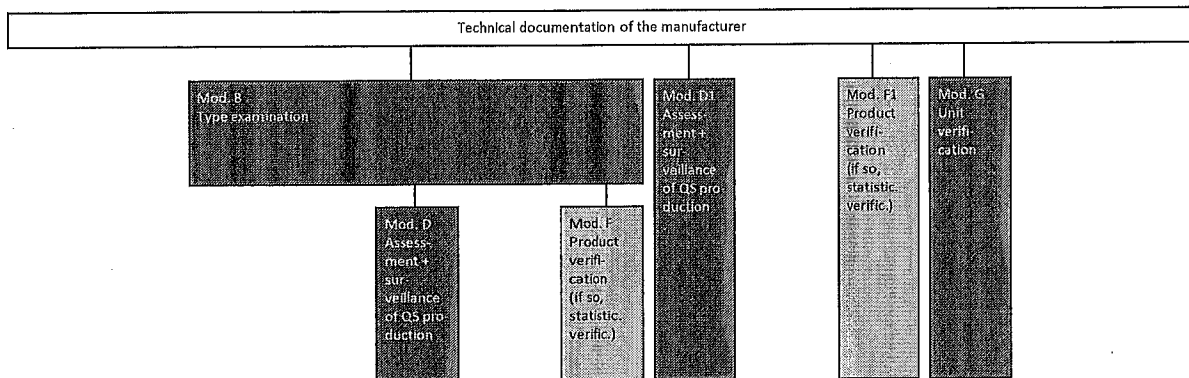
PTB-Offer:
Modules B, D, D1, G



- 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:
 - mechanical systems: B+D, B+E, B+F, D1, F1, G, H1
 - electromechanical systems: B+D, B+E, B+F, G, H1
 - electronic systems or systems containing AWI: B+D, B+F, G, H1
- MI-007, Taximeters: B+D, B+F, H1
- MI-008, Material measures:
 - I – Material measure of length: B+D, D1, F1, G, H
 - II – Capacity serving measures: A2, B+D, B+E, D1, E1, F1, H
 - mechanical or electromechanical: B+D, B+E, B+F, D1, E1, F1, G, H, H1
 - electronic or with SW: B+D, B+F, G, H1
- MI-009, Dimensional measuring instruments: B+D, B+F, H1
- MI-010, Exhaust gas analysers: B+D, B+F, H1



PTB-Offer:
Modules
B, D, D1, G, H1
* H1 only for
MI-001 and MI-004



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

German Measures and Verification Ordinance (MessEV):

<https://www.gesetze-im-internet.de/messev/MessEV.pdf>

See annex 4:

- Part 1 „General provisions“
- Part 2 „Details of conformity assessment procedures“

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

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014L0032>

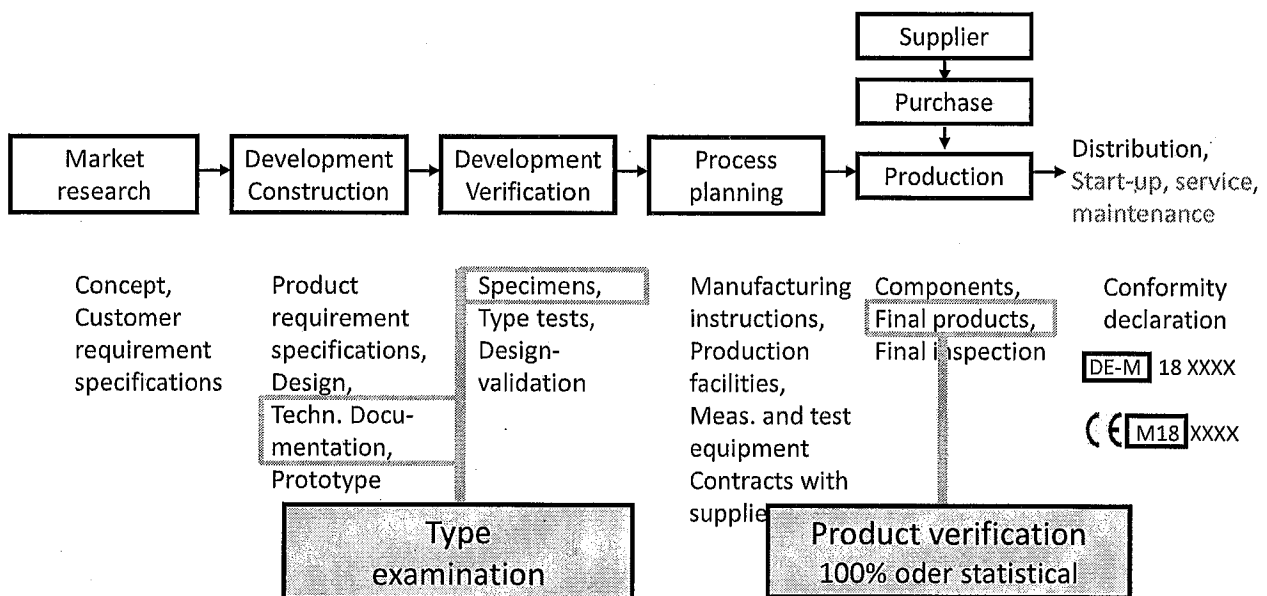
See annex II

European Directive on Nonautomatic Weighing Instruments 2014/31/EU (NAWID):

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014L0031>

See annex II

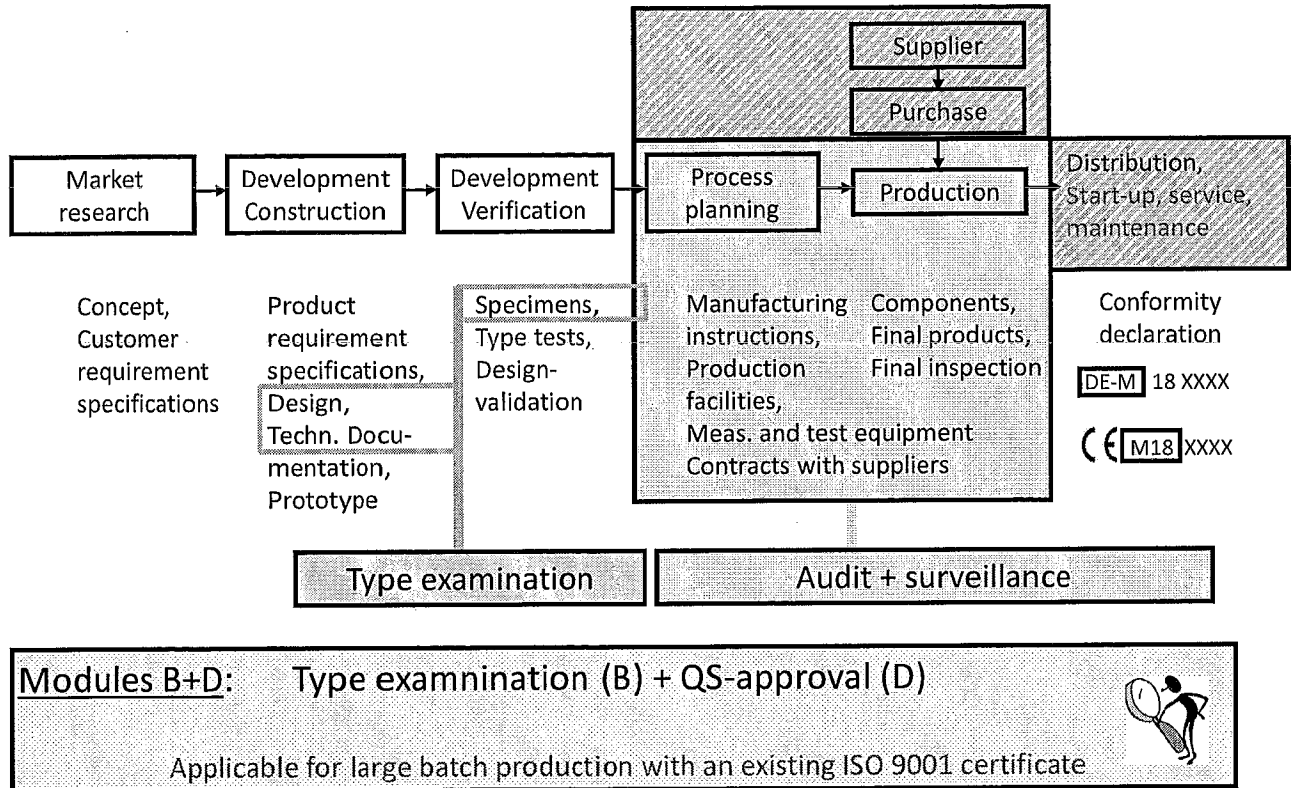
Module combination B+F



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

Applicable for small batch production
(Comparable to former type approval and verification)

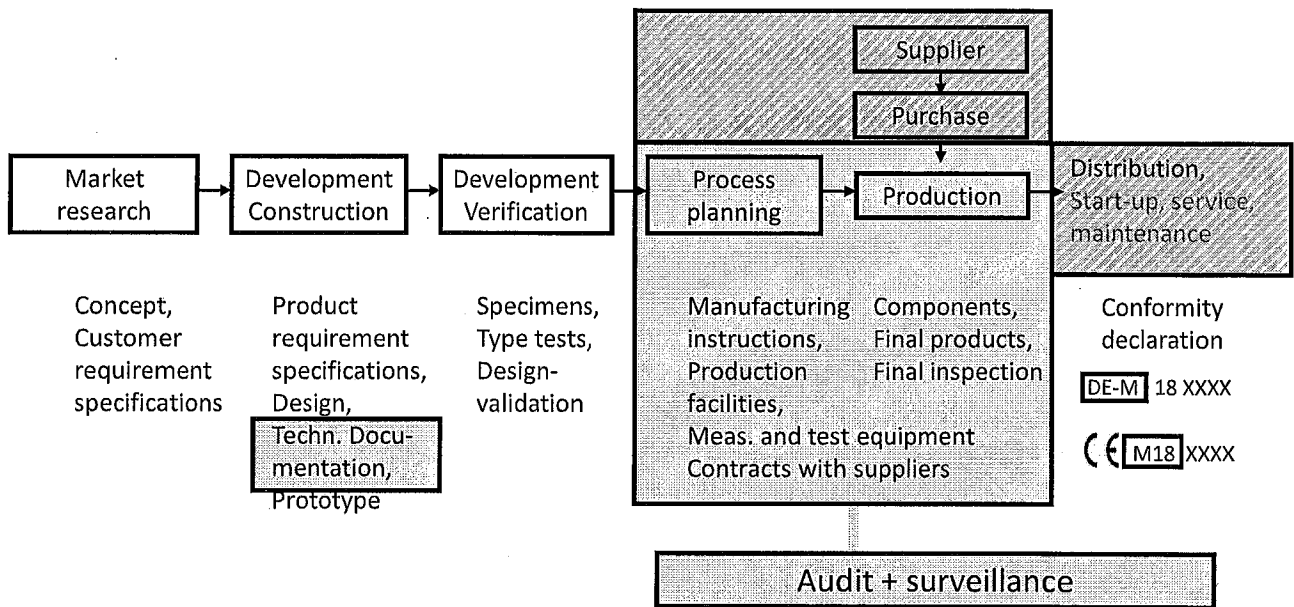




Requirements to the quality system

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.



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



Structure

- Introduction
- Comparison ISO 9001-certification / QS-approval
- Procedure QS-approval
- Contact



	ISO 9001-Certification	QS-Approval
Purpose of Quality-System	Compliance with customer requirements Decrease of failure costs Continuous improvement	Securing of the compliance of measuring instruments with legal requirements
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:

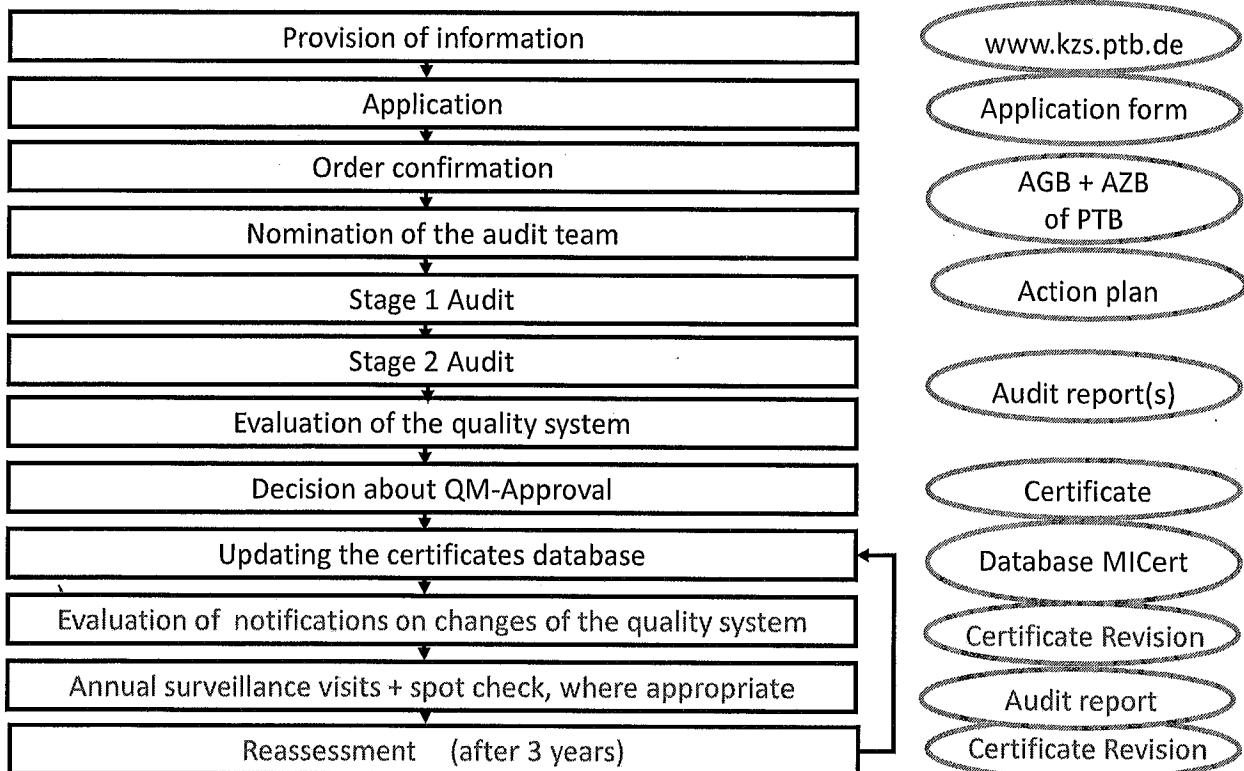
WELMEC Guide 8.6

- Non- Automatic Weighing Instruments Directive 2014/31/EU - Presumption of Conformity of the Quality System of Manufacturers with Module D when EN ISO 9001:2015 is applied
- Measuring Instruments Directive 2014/32/EU - Presumption of Conformity of the Quality System of Manufacturers with Module D or H1 when EN ISO 9001:2015 is applied

<https://www.welmec.org/documents/guides/86/>

- Introduction
- Comparison ISO 9001-certification / QS-approval ✓
- Procedure QS-approval
- Contact

Procedure of the QS-Approval





- 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 (if existing)
- List of all QS-documents 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

P.1

 Physikalisch-Technische Bundesanstalt Braunschweig und Berlin Nationales Metrologieinstitut	
 Zertifikat Certificate	
über die Anerkennung eines Qualitätssicherungssystems <i>on the approval of a quality system</i>	
Ausgestellt für: Issued to:	<Firmenname> <des Zertifikatsinhabers> <Straße> <Plz> <Ort> <LAND>
gemäß: in accordance with:	Mess- und Eichverordnung vom 11. Dezember 2014 (MessEV) in Verbindung mit Richtlinie 2014/31/EU vom 26. Februar 2014 (NAWID) und mit Richtlinie 2014/32/EU vom 26. Februar 2014 (MID) <i>Measures and Verification Ordinance dated 11 December 2014 (MessEV) in connection with Directive 2014/31/EU of 26 February 2014 (NAWID) and with Directive 2014/32/EU (MID)</i>
Messgröße lt. MessEV § 1: <i>Measurement acc. to Measures and Verification Ordinance, section 1</i>	<Messgröße 1 gemäß MessEV § 1 (deutsch)> <Messgröße 1 gemäß MessEV § 1 (englisch)> <Messgröße 2 gemäß MessEV § 1 (deutsch)> <Messgröße 2 gemäß MessEV § 1 (englisch)>
Nr. des Zertifikats: Certificate No.:	DE-M-AQ-PTB<XX>, Revision <XX>
Gültig bis: valid until:	<TT.MM.JJJJ>
Anzahl der Seiten: Number of pages:	<AnzSeiten>
Geschäftszeichen: Reference No.:	PTB-Q.32-<xxxxxxx>
Nr. der Stelle: Body No.:	0102
Im Auftrag On behalf of PTB	Braunschweig, <TT.MM.JJJJ> Siegel Seal
<Zertifizierer>	

QS-Approval Certificate



P.2



Physikalisch-Technische Bundesanstalt
Braunschweig und Berlin
Nationales Metrologieinstitut

Seite 2 des QS-Anerkennungszertifikats Nr. DE-M-AQ-PTBXXX, Revision xx, vom TT.MM.JJJJ
Page 2 of QS Approval Certificate No. DE-M-AQ-PTBXXX, Revision xx, dated TT.MM.JJJJ

Zertifikatsgeschichte
History of the Certificate

Ausgabe Issue	Datum Date	Änderungen Modifications
DE-M-AQ-PTBXXX, Revision 00	<TT.MM.JJJJ>	Erstbescheinigung Initial certificate
DE-M-AQ-PTBXXX, Revision 01	<TT.MM.JJJJ>	

»nachfolgendem Absatz bei Erstbescheinigung streichen«

Diese Revision «XX» ersetzt die Revision «XX-1» der Bescheinigung Nr. DE-M-AQ-PTB-«XX» vom «tt.mm.yyyy», Gesellschaften PTB-32-«xxxxxx».
This Revision «XX» replaces Revision «XX-1» to Certificate No. DE-M-AQ-PTB-«XX» dated «tt.mm.yyyy», Reference No. PTB-Q-32-«xxxxxx».

Geltungsbereich
Scope of validity

Die Konformitätsbewertungsstelle der Physikalisch-Technischen Bundesanstalt (PTB) bescheinigt mit diesem Zertifikat, dass das Qualitätssicherungssystem in dem in diesem Zertifikat genannten Geltungsbereich den folgenden Anforderungen entspricht:
By means of this Certificate, the Conformity Assessment Body of the Physikalisch-Technische Bundesanstalt (PTB) certifies that the Quality System complies within the scope of validity specified in this Certificate with the following requirements:

- Anlage 4 Modul D der Mess- und Eichverordnung vom 11.12.2014 (BGBI I S. 2010), Abs. 3.2 u. 3.3
Annex 4 Module D of the Measures and Verification Ordinance dated 11.12.2014 (Federal Law Gazette I, p. 2010), sections 3.2 and 3.3
- Anlage 4 Modul D1 der Mess- und Eichverordnung vom 11.12.2014 (BGBl. I S. 2010), Abs. 3.2 u. 3.3
Annex 4 Module D1 of the Measures and Verification Ordinance dated 11.12.2014 (Federal Law Gazette I, p. 2010), sections 3.2 and 3.3
- Anhang II Modul D der Richtlinie 2014/31/EU des Europäischen Parlaments und des Rates vom 26. Februar 2014 zur Angleichung der Rechtsvorschriften der Mitgliedstaaten betreffend die Bereitstellung nichtbenutzter Waagen auf dem Markt (ABl L 96 S. 107), zuletzt geändert durch Berichtigung vom 20.01.2016 (ABl L 13 S. 61), Abs. 2.2.
Annex II Module D of Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments (OJ L 96 p. 107), last amended by Correction of 20.01.2016 (OJ L 13 p. 61) section 2.2
- Anhang II Modul D1 der Richtlinie 2014/31/EU des Europäischen Parlaments und des Rates vom 26. Februar 2014 zur Angleichung der Rechtsvorschriften der Mitgliedstaaten betreffend die Bereitstellung nichtbenutzter Waagen auf dem Markt (ABl L 96 S. 107), zuletzt geändert durch Berichtigung vom 20.01.2016 (ABl L 13 S. 61), Abs. 3.6.2.
Annex II Module D1 of Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments (OJ L 96 p. 107), last amended by Correction of 20.01.2016 (OJ L 13 p. 61) section 3.6.2
- Anhang II Modul D der Richtlinie 2014/32/EU des Europäischen Parlaments und des Rates vom 26. Februar 2014 zur Harmonisierung der Rechtsvorschriften der Mitgliedstaaten über die Bereitstellung von Messgeräten auf dem Markt (ABl L 96 S. 140), zuletzt geändert durch Berichtigung vom 20.01.2016 (ABl L 13 S. 67) Abs. 3.2.
Annex II Module D of Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (OJ L 96 p. 140), last amended by Correction of 20.01.2016 (OJ L 13 p. 67) section 3.2

Physikalisch-Technische Bundesanstalt
Konformitätsbewertungsstelle (Conformity Assessment Body)
Bundesallee 100
38116 Braunschweig
DEUTSCHLAND / GERMANY

Abzählzettel 2-12
1007 Berlin
DEUTSCHLAND / GERMANY

P.3



Physikalisch-Technische Bundesanstalt
Braunschweig und Berlin
Nationales Metrologieinstitut

Seite 3 des QS-Anerkennungszertifikats Nr. DE-M-AQ-PTBXXX, Revision xx, vom TT.MM.JJJJ
Page 3 of QS Approval Certificate No. DE-M-AQ-PTBXXX, Revision xx, dated TT.MM.JJJJ

Annex I (Module D of Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (OJ L 96 p. 140), last amended by Correction of 20.01.2016 (OJ L 13 p. 67) section 3.2.
Anhang II Modul D1 der Richtlinie 2014/32/EU des Europäischen Parlaments und des Rates vom 26. Februar 2014 zur Harmonisierung der Rechtsvorschriften der Mitgliedstaaten über die Bereitstellung von Messgeräten auf dem Markt (ABl L 96 S. 140), zuletzt geändert durch Berichtigung vom 20.01.2016 (ABl L 13 S. 67) Abs. 6.2.
Annex II Module D1 of Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (OJ L 96 p. 140), last amended by Correction of 20.01.2016 (OJ L 13 p. 67) section 6.2.

Der Zertifikatsinhaber ist berechtigt, die Kennzeichnung für die im Geltungsbereich dieses anerkannten Qualitätssicherungssystems gefertigten Messgeräte mit der PTB-Kennnummer 0102 zu versehen. Die Bewertung basiert auf einer Begutachtung der eingereichten Dokumente und einem Audit im Unternehmen. Das Qualitätssicherungssystem unterliegt der laufenden Überwachung der Konformitätsbewertungsstelle.
The owner of this Certificate is entitled to provide the marking of the measuring instruments which have been produced within the scope of validity of this approved Quality System with the PTB identification number 0102. The assessment is based on an evaluation of the submitted documents and on an audit on site. The quality system is subject to permanent surveillance by the Conformity Assessment Body.

Standorte und Gerätearten
Sites and kinds of instruments

Standort 1: site 1:	<Standort_1p> <Straße/Hausnr.> <PLZ> <Ort> (<Land>)
Messgerätearten: kinds of measuring instruments:	<Geräteart (deutsch)> <Geräteart (englisch)>
Standort 2: site 2:	<Standort_2p> <Straße/Hausnr.> <PLZ> <Ort> (<Land>)
Messgerätearten: kinds of measuring instruments:	<Geräteart (deutsch)> <Geräteart (englisch)>

Die Konformitätsbewertungsstelle führt eine Liste der von diesem Zertifikat abgedeckten Messgerätetypen. Die Liste wird laufend aktualisiert und dem Inhaber des Zertifikats zugesichert.
The Conformity Assessment Body administers a list of measuring instrument types covered by this Certificate. The list will be kept up to date and sent to the owner of the certificate.

Physikalisch-Technische Bundesanstalt
Konformitätsbewertungsstelle (Conformity Assessment Body)
Bundesallee 100
38116 Braunschweig
DEUTSCHLAND / GERMANY

Abzählzettel 2-12
1007 Berlin
DEUTSCHLAND / GERMANY

Physikalisch-Technische Bundesanstalt ■ Braunschweig und Berlin

Page 21

List of measuring instrument types



Physikalisch-Technische Bundesanstalt

Braunschweig und Berlin
Konformitätsbewertungsstelle/Conformity Assessment Body



Physikalisch-Technische Bundesanstalt
Braunschweig und Berlin

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:

Typbezeichnung Type designation	Geräteart Device type	Nr. der BPB*/Bauartzulassung** No. of TEC*/ Type approval**	Fertigungsstandort Production site	Bemerkungen Remarks

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

Typbezeichnung Type designation	Geräteart Device type	Nr. der BPB* / Bauartzulassung** No. of TEC* / Type approval**	Fertigungsstandort Production site	Kunde Customer	Bemerkungen Remarks

* 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 mitteilungs-pflichtig/Any changes have to be notified to PTB.

Braunschweig, <Datum>

Im Auftrag
On behalf of PTB

Siegel
Seal

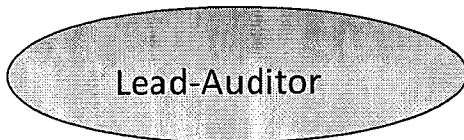
Physikalisch-Technische Bundesanstalt ■ Braunschweig und Berlin

Page 22

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:



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. 1.000 € /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

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

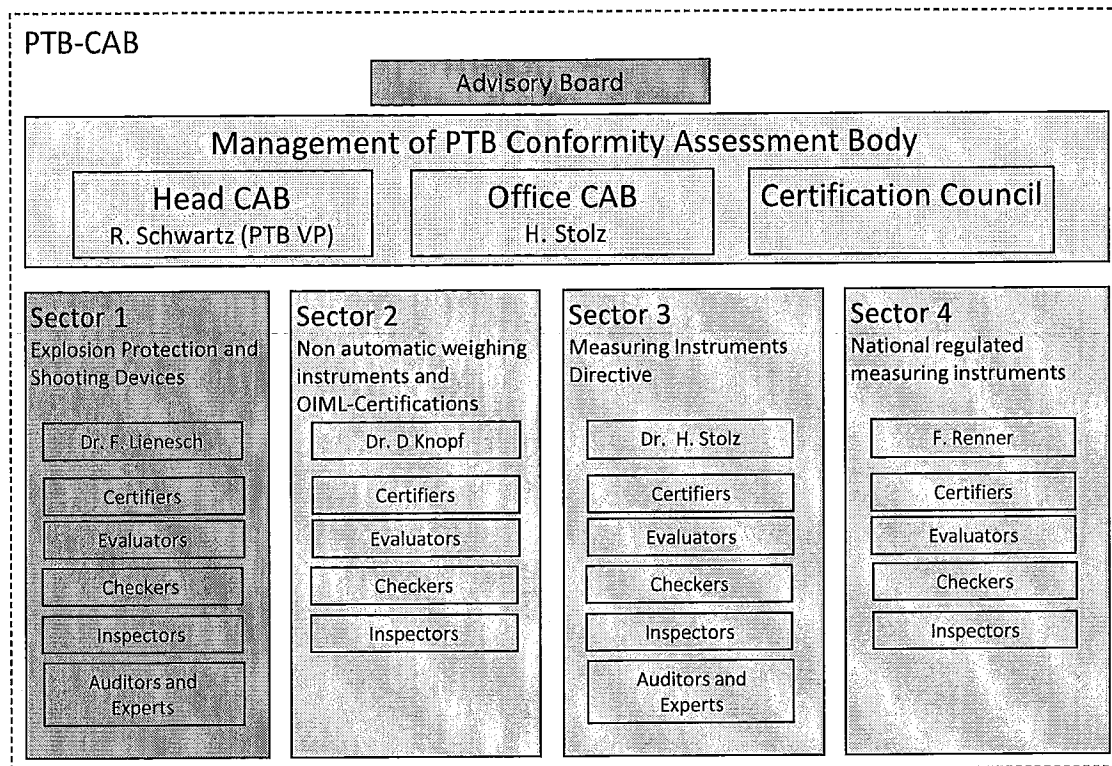
-> review by the notified body

-> potential changes of QS-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
 Measuring instruments for liquids
 Measuring instruments for gas
 Measuring instruments for thermal energy
 Measuring instruments for electrical energy
 Weighing Instruments
 Measuring instruments of the grading of cereals and oilseeds
 Densimeters and contentmeters
 Measuring instruments for temperature
 Pressure gauges
 Measuring Instruments for traffic control
 Exhaust gas analysers
 Measuring devices for diary examinations
 Taximeters
 Sound level meters
 Measuring Instruments for Radiation Protection
 Software in Measuring Instruments

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Oliver Hupe	Tel. +49 531/592-6310
Marko Esche	Tel. +49 30/3481-7975

General questions concerning modules B or G :

Non Automatic Weighing Instruments
 OIML-Certifications
 Measuring Instruments Directive
 Domestic regulated Measuring Instruments

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Dorothea Knopf	Tel. +49 531/592-1100
Harry Stolz	Tel. +49 531/592-9220
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PTB working group 9.22:

Markus Urner,
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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

-> <https://www.ptb.de/cms/ptb/fachabteilungen/abt9/fb-92/ag-922.html>

General questions



General questions on legal metrology in Germany:

PTB Working Group Legal Metrology (9.21)

Dr. Mäuselein sascha.maeuselein@ptb.de

General questions on conformity assessment services of PTB:

Office PTB-CAB (9.22)

Dr. Stolz harry.stolz@ptb.de

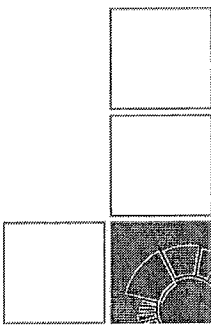
Other CABs:

Domestic:

<http://www.adkbs.ptb.de/>

European:

<http://ec.europa.eu/growth/tools-databases/nando/>



**Physikalisch-Technische Bundesanstalt
Braunschweig und Berlin**

Conformity Assessment Body

Bundesallee 100

38116 Braunschweig

<https://www.ptb.de/cms/ptb/fachabteilungen/abt9/fb-92/ag-922.html>