

Instruction Sheet for Manufacturers

Instructions for placing measuring instruments on
the market in accordance with the Verification Act

Instruction Sheet for Manufacturers

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Information on the Internet at <http://www.ptb.de>

- General information on legal metrology in the section "Thematic tours", "In the service of the public".
- Provisions and regulations with regard to legal metrology in the section "Publikationen", "**Publikationen des gesetzlichen Messwesens**" (available in German only).
- Device-specific information and instruction sheets in the section "**Dienstleistungen**", "Prüfen und Zertifizieren", "Zertifikate nach dem Eichgesetz" or "Zertifizierungsstellen" (available in German only).

Amendments regarding Instructions as of May 2008

Ausgabe	Abschnitte	Bemerkungen
July 2008	Instruction, Annex A, B	Legal references to Verification Act have been updated (Note 1), Annex A and B
February 2009	Instruction Annex A	Contents No A.4
March 2009	Annex C	Responsible departments have been changed (EO 16, EO 18-8)
April 2009	Instruction, Annex C	Legal references to Verification Ordinance were updated (Note 2), Annex C
August 2009	Instruction Annex A	References to the directives 90/384/EEC and 71/316/EEC were updated to 2009/23/EC and 209/34/EC.
May 2010	Annex C	Contact persons have been updated (EO 9, 10, 11, 18, 21, 22, 23)
July 2010	Instruction Annex A, B	Legal references in No 3.2 und 3.3 have been changed. Annex A in A5 und A6 adpted. In Annex B: Notification of PTB was extended.
June 2011	Instruction Annex C	Legal reference were updated (page 3, 6, Annex C)
Oktober 2011	Anhang C	Änderungen der Fachbereiche zu EO 22

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Dear Sir or Madam,

This "Instruction Sheet for Manufacturers" is intended to inform you - as manufacturers - about the certificates required for measuring instruments underlying the Verification Act¹ and the Verification Ordinance (EO)², as well as the EC Directives having been transposed into the EO. Both corpora of regulations are part of the regulatory law of the economy and are intended (a) to protect the consumer from false measurement results and (b) to ensure the reliability of measuring instruments used in commercial and official transactions as well as in health, labour and environmental protection. For these applications it is, as a matter of principle, required to use measuring instruments that have been verified, to ensure measurement reliability.

A manufacturer is - according to the Verification Act - someone who places measuring instruments on the market in his own name or commissions them for his own purposes and assumes responsibility for complying with the provisions stated in the Verification Act.

If you have any questions on a particular category of measuring instruments, please do not hesitate to get in touch with the contact persons listed in Annex C.

1 Mandatory verification

The obligation to use verified measuring instruments (mandatory verification) derives from the Verification Act and the Verification Ordinance. For the applications mentioned in these regulations, the quantities must, as a matter of principle, be determined by means of measuring instruments which have been verified.

Measuring instruments which are subject to mandatory verification must be acceptable for verification; they must be tested and stamped (verification) in accordance with the regulations of the Verification Ordinance (EO). Due to the implementation of harmonised European Directives, further procedures for the commissioning of measuring instruments subject to legal verification have been included in the verification legislation.

The ancillary devices of measuring instruments are treated as equivalents to measuring instruments. Mandatory verification also extends to ancillary devices which serve to determine, represent, disseminate or process measurement results.

2 Admissibility for verification and declaration of conformity

2.1 Fundamentals

The measuring instruments regulated within the scope of the verification legislation shall, with regard to their reliability, comply with the Verification Ordinance and the recognised technical rules. In the Verification Ordinance, the fundamental requirements are laid down which must be fulfilled by measuring instruments subject to legal verification. Verification is a legal measure, intended to ensure the reliability of measuring instruments.

A measuring instrument is admissible for verification when it can be verified or when its conformity (with an EC Directive) has been declared. In the Verification Ordinance, the following procedures are defined according to the type of measuring instrument:

1. type approval (or general approval) for national verification
for, e.g., measuring callipers, log measuring devices, level gauges, transport volumetric tanks, calorific value determination devices, moisture meters, electric thermometers, speed-monitoring instruments, exhaust meters (for diesel engines), sound-level meters, cold meters, dosimeters for radiation protection
2. EEC type approval (or general approval) for EEC initial verification
for grain probes, evidential breath analysers, tyre-pressure gauges, weights.

¹Metrology and Verification Act (Verification Act) of March 23, 1992, last amended by the Law of March 7, 2011 (Fed. Law Gaz. I, p. 338).

²Verification Ordinance dated August 12, 1988, last amended by the Ordinance dated from June 6, 2011 (Fed. Law Gaz. I, p. 1035).

3. EC type approval and EC verification according to Directive 2009/23/EC for non-automatic weighing instruments.
4. conformity assessment procedures according to Directive 2004/22/EC for water meters and volume conversion devices, active electricity meters, heat meters, measuring systems for the continuous and dynamic measurement of quantities of liquids other than water, automatic weighing instruments, taximeters, material measures as length measures and capacity serving measures, length measuring instruments and their combinations, exhaust gas analysers (extraneous ignition).

The detailed assignment of the different types of measuring instruments to the respective procedures can be found in Annex C.

Whereas measuring instruments with national or EEC type approval may be used for purposes subject to legal verification only after having passed the initial verification, the measuring instruments having been placed on the market according to procedures Nos. 3 and 4 may be used at once for purposes subject to legal verification. They are considered as having passed initial verification.

The manufacturer must commission a notified body of his choice with the realisation of the conformity assessment procedures defined in Directives 2009/23/EC and 2004/22/EC. You will find a list of notified bodies and their tasks at the EU Internet portal "NANDO".

2.2 Type approval for national verification, general approval

Approval and verification are the classic procedures of legal verification. The (national) type approval is the type approval of categories of measuring instruments for national verification and is only valid in the Federal Republic of Germany. In the Verification Ordinance it is laid down whether measuring instruments are, as a rule, admissible for verification on the strength of their design and their properties, or whether their type has to be approved for verification by PTB. The measuring instrument categories must meet the requirements which are only valid at the national level. Approved measuring instruments are admissible for verification.

2.3 EEC type approval for EEC initial verification, general approval

The EEC type approval is the type approval of measuring instrument categories for EEC initial verification and is valid in all member states having ratified the agreement on the European Economic Area (EEA states). It is granted on the basis of the Framework Directive 2009/34/EC³ and of an optional EEC directive⁴ (separate directive) when the type meets the requirements of the corresponding separate directive. For measuring instruments of simple design, a type approval can be waived in this directive; these instruments are then generally considered as having been approved. The separate directives contain all the requirements of the corresponding types and have been fully included in the Verification Ordinance. Measuring instruments with an EEC type approval are admissible for verification. They may also receive national initial verification.

2.4 EC type approval and EC verification according to Directive 90/384/EEC⁵

The EC type approval is that part of the procedure according to Annex II.1 of Directive 2009/23/EC (NAWI Directive) in which a notified body certifies that the type of a non-automatic weighing instrument meets the requirements of this directive. The EC type approval is valid in all EEA member states. Non-automatic weighing instruments must fulfil the fundamental requirements according to Annex I of the NAWI Directive.

For the EC verification, the conformity of the individual non-automatic weighing instrument with the NAWI Directive and the type described in the EC type approval⁶ is assessed. The

³ Before 18.05.2009 was in force the Directive 71/316/EEC

⁴ The optional EEC directives adopted before 1989 specify complete technical requirements whereby, for the same measuring instrument, there may be deviating additional requirements at the national level.

⁵ In the directives that have been issued since 1989 according to the "New Approach", only the complete harmonisation of fundamental requirements is envisaged; deviating national requirements may no longer be stated.

manufacturer declares conformity either on the basis of routine tests of each separate weighing instrument carried out by a notified body according to Annex II.3 or on the basis of his quality management system for the production of weighing instruments according to Annex II.2, which is recognised and checked by a notified body. Weighing instruments with EC verification are considered as having passed initial verification.

2.5 Conformity assessment procedures according to Directive 2004/22/EC

The manufacturer declares the conformity of his devices with Directive 2004/22/EC (MID) within the scope of a conformity assessment procedure. The manufacturer can thereby choose from the different procedures stated in the device-specific annexes to the MID. The conformity assessment procedures are composed of modules or module combinations which can encompass the areas "production and final control", but also the areas "development and design" of the measuring devices. They require the involvement of a notified body. From the conformity assessment procedures prescribed for each category of measuring instruments, the manufacturer may select the one which is the most favourable to him.

See: **MID-Gerätearten** on PTB's website, under "Publikationen", "Publikationen des gesetzlichen Messwesens" (available in German only).

Measuring instruments which have gone through the conformity assessment procedure and are properly marked, are considered as having been initially verified.

2.5.1 EC type examination (Annex B)

The EC type examination (Annex B) is that part of a conformity assessment procedure in which a notified body assesses the technical draft of a measuring instrument and certifies that the basic requirements of Annex I and of the corresponding device-specific Annex of the MID are complied with. EC type test certificates are valid in all EEA states.

An EC type examination has to be combined with procedures according to Annexes F, D or E.

2.5.2 EC design examination

The EC design examination is an integral part of the conformity assessment procedure according to Annex H1, in which the manufacturer declares the conformity of measuring instruments with the MID on the basis of a comprehensive quality assurance system.

The notified body, which is simultaneously in charge of the recognition of the comprehensive QM system of the manufacturer, assesses whether the design of a measuring instrument category fulfils the MID requirements valid for this measuring instrument. The EC design examination certificate is valid in all EEA states. It encompasses the categories of measuring instruments underlying the comprehensive QM system.

2.5.3 Declaration that conformity with the type is given on the basis of quality management systems (Annexes D, E, H1)

In the conformity assessment procedures according to Annexes D, E or H1, the manufacturer declares that the conformity of the measuring instruments to the type is given on the basis of quality assurance. For this purpose, he must operate a suitable quality management system which has been recognised by a notified body and is regularly checked by same. The quality management system must encompass the product (Annex E), the manufacturing, the final inspection and the testing of the measuring instruments (Annex D) or the entire manufacturing process including the development (Annex H1).

The notified body assesses the quality management system in order to establish whether it ensures compliance of the measuring instruments with the type described in the EC type examination certificate or, in the case of Annex H1, with the type described in the EC design

⁶ According to Art. 8, Para. 1a) of the NAWI, the EC type approval is not required for weighing instruments which use no electronic device or whose load measuring device is not equipped with a spring to balance out the introduced load.

examination certificate, as well as with the corresponding requirements of the directive. The notified body issues a certificate of the QM recognition to the manufacturer.

In the case of the procedures according to Annexes D1 or E1, the combination with the type examination (Annex B) is waived and in the case of the procedures according to Annex H, the combination with the design examination of Annex H1 is, too. For the rest, the procedures are analogous to those of Annexes D, E and H1.

2.5.4 Declaration that conformity with the type is given on the basis of a product test (Annex F)

In the case of the procedure according to Annex F, the manufacturer declares - on the basis of routine tests of the measuring instruments which are carried out by or commissioned by a notified body - that conformity of the measuring instruments to the type is given. The tests may be carried out on each measuring instrument or be based on statistic tests. This procedure corresponds basically to what used to be the initial verification.

In the case of the procedure according to Annex F1, the combination with the type examination (Annex B) is waived. This procedure is comparable to the previous initial verification of generally approved measuring instrument categories.

2.5.5 Declaration of conformity on the basis of a single test (Annex G)

In the case of the procedure according to Annex G, the manufacturer declares - on the basis of a single test of the measuring instrument, which is carried out by or commissioned by a notified body - that conformity of the measuring instruments with the MID is given. Instead of a type examination, the manufacturer provides the notified body with the technical documentation on the measuring instrument category.

3 Competencies

The competencies derive from the Verification Act and the Verification Ordinance.

3.1 Type approvals

PTB is the point of contact and is responsible for national type approvals for measuring instruments and for ancillary devices subject to legal verification, as well as for type approvals according to an EEC directive.

Applications for type approval must be submitted to the certifier in charge. You will find further information on how to apply in Annexes A or B; the certifiers in charge at PTB are listed in Annex C of this Instruction Sheet.

For these official duties, PTB charges fees within the scope of the "Regulations Governing Charges for Approval"⁷, according to the actual amount of work arising.

3.2 Conformity assessment procedure of Directive 2009/23/EC

PTB is a notified body for EC type approval according to Annex II.1 for non-automatic weighing instruments (see section 2.4). Furthermore, PTB issues test certificates for modules and ancillary devices of weighing instruments. These services are invoiced according to the *Regulations Governing Charges for Services Supplied*⁸, according to the actual amount of work arising.

In Germany, notified bodies for Annexes II.2 and II.3 of the NAWI Directive (see section 2.4) are, amongst others, the verification authorities of the federal states.

⁷ Regulations on the fees for the type approval of measuring instruments for verification (Regulations Governing Charges for Approvals) of December 22, 1992 (Fed. Law Gaz. I, p. 2471), last amended by the Ordinance of October 18, 2010 (Fed. Law Gaz. I, p. 1430).

⁸ Regulations Governing Charges for Services Supplied by the PTB of December 17, 1970 (Fed. Law Gaz. I, p. 1745), last amended by the Ordinance of October 5, 2009 (Fed. Law Gaz. I, p. 3542).

3.3 Conformity assessment procedure of Directive 2004/22/EC

PTB is a notified body for all measuring instruments of the MID with regard to the conformity assessment procedures according to Annexes B, D and H1 (see sections 2.5.1, 2.5.2 and 2.5.3). These services are invoiced according to the *Regulations Governing Charges for Services Supplied by PTB*, according to the actual amount of work arising.

Further notified bodies - also for the conformity assessment procedures which are not offered by PTB - can be found in the "NANDO" database.

3.4 PTB certificates

To summarise sections 3.1 to 3.3, PTB, upon application, issues the following certificates in compliance with the Verification Act:

1. National type approval certificate (see section 2.2);
2. EEC type approval certificate (see section 2.3);
3. EC type approval certificate (NAWI Directive) (see section 2.4);
4. EC type examination certificate (MID) (see section 2.5.1);
5. EC design examination certificates (MID) (see section 2.5.2);
6. Recognitions of quality management systems according to Annexes D and H1 (MID) (see section 2.5.3).

The PTB cooperates closely with the approval authorities of the other member states of the EEA as well as with the other notified bodies, and its employees contribute substantially to the preparation of international legal provisions and standards.

3.5 Verification

In Germany, the verification authorities are the authorities which are in charge of the national and EEC initial verification of measuring instruments subject to legal verification; they are appointed by the 16 federal states. The verification of instruments for measuring electricity, gas, water and heat is mainly carried out by state-approved test centres. For further information, please consult www.eichamt.de.

Annex A: Type approval / Type examination / Design examination

Annex A deals with applications for and the granting of the following certificates:

1. National type approval certificate (see section 2.1);
2. EEC type approval certificate (see section 2.2);
3. EC type approval certificate (NAWI Directive) (see section 2.3);
4. EC type examination certificate (MID) (see section 2.4.1);
5. EC design examination certificates (MID) (see section 2.4.2);

A.1 How to file an application

We recommend that you contact the certifier in charge at PTB (see Annex C) as early as in the development phase and obtain information on the legal requirements at that stage.

A1.1 Informal application

Please submit an informal written application to the certifier in charge at PTB (see Annex C). According to section 23 of the German Administrative Proceedings Law (Verwaltungsverfahrensgesetz - VwVfG), the application must be written in German; applications for EC type or EC design examination certificates may also be formulated in English.

If you submit the application as an authorised representative of the manufacturer, please prove that you have been authorised by the manufacturer. Authorised representatives must - except in the case of national type approvals - be domiciled in a member state of the European Union or another signatory state of the European Economic Area (EWR).

For the formal processing of the applications, PTB needs the following information:

- a) Name and address of the manufacturer and, if the application is submitted by an authorised representative, also his/her name and address;
- b) the designation of the measuring instrument category;
- c) the intended use and the metrological features of the measuring instrument;
- d) trade name or designation of the measuring instrument.
- e) A written declaration - except in the case of national type approvals - stating that this application has not been submitted in any other EEA signatory state or to any other notified body.

Please indicate any existing certificates or test reports having been issued for parts of the measuring instrument or any approvals issued previously by PTB.

If metrological properties of the type have already been confirmed within the scope of previous tests, the reference document (test report or approval certificate) should be indicated and the confirmed metrological properties should be explicitly stated. This might speed up the assessment procedure.

A1.2 Documents needed for the application

After consulting the certifier in charge, please enclose the following documents in your application:

- f) the instruction manual;
- g) a general description of the design and functioning of the measuring instrument;
- h) drawings and wiring diagrams of components, sub-assemblies, circuits, etc.;
- i) if applicable, a description of the electronic elements with drawings, diagrams, flowcharts;
- j) for interfaces on measuring instruments and ancillary devices: wiring diagrams and descriptions of the interface instructions and of the instrument functions that can be triggered;

- k) in the case of measuring instruments equipped with software:
general information about the software, with an explanation of its characteristics and functioning (control levels, program sequence scheme), description and measures for the separation of the functions that are subject to verification from those that are not;
- l) if applicable, printouts of measurement results and test reports, e.g. EMC test;
- m) indications as to where to apply protection stamps and markings
as well as,
- n) if applicable, specimens.

In the case of applications for **EC type** or **design examination certificates** according to MID, the following additional documents have to be submitted (see Art. 10 MID):

- o) indications (descriptions) of the production methods by which a uniform manufacturing of the measuring instruments and their components is ensured;
- p) a list of the harmonised standards and/or normative documents fully or partially applied in production;
- q) a description of the technical solutions chosen if the MID-related standards and/or normative documents mentioned have not been applied; and, if applicable, the results of tests carried out in appropriate laboratories of the manufacturer or in another testing laboratory on his behalf and under his responsibility;
- r) the results of constructive calculations⁹, tests, etc.:
- s) if necessary, suitable test results by means of which it can be proven that the instruments fulfil the requirements of the directive under the specified rated operating conditions and in the presence of the prescribed environment-related faults, or that the stability requirements of gas, water and heat meters as well as of metering systems for liquids other than water are complied with.
- t) the EC type or design examination certificates for instruments which contain parts identical to those of the design;
- u) if applicable, indications of the manufacturer on the conditions of compatibility with interfaces and sub-assemblies.

For the **EC design examination certificate**, there is no need to submit a specimen. The manufacturer must be able to carry out the assessment of the type himself within the scope of his recognised QM system.

For the individual measuring instrument categories, further special regulations may exist. Please consult the information available on the Internet at www.ptb.de, under "Dienstleistungen", "Prüfen und Zertifizieren" on the range of services offered by each of the departments about "**Zertifikate nach dem Eichgesetz**" (certificates according to the Verification Act).

A1.3 Confirmation of application

You will receive a written confirmation that the application has been accepted, including, if applicable, a list of the documents and samples you will have to submit in addition.

The application can be processed by PTB only when all documents have been submitted and, if applicable, if the necessary specimens are available for testing.

A2 Testing of the type or design and issuing of the certificate

A2.1 General

During the tests, it is checked whether compliance with the requirements of the Verification Act and the Verification Ordinance or with the EC directives transposed into the Verification Ordinance is given. The Verification Ordinance only lays down basic requirements. The

⁹ (relevant to metrological applications)

measuring instruments must continue to comply with the accepted rules of technology. If harmonised rules are applied, it can be assumed that the basic requirements are met. If there are deviations from these, it must be investigated - when testing the type/design - whether the basic requirements are met.

A list of the regulations and accepted rules of technology for measuring instruments pursuant to the Verification Ordinance is published by PTB and updated at regular intervals. The current list can be consulted on PTB's website under "**Publikationen des gesetzlichen Messwesens**" (available in German only).

After the tests have been passed, PTB issues a certificate to the applicant.

The approval or conformity assessment of the measuring instrument type is carried out on the basis of the verification law. Other regulations, e.g. for health, labour and environmental protection or safety technology, as well as protective rights of any kind are not generally part of the scope of type or design testing even if they may be a prerequisite for the operation of a measuring instrument.

A2.2 Processing time

If the specifications of the PTB requirements or harmonised standards are met, it may be assumed that the processing time will be shorter than for designs of measuring instruments deviating from such specifications. The employees at PTB endeavour to issue the certificates within three months. As experience has shown, delays will have to be expected if, for example, the documentation is not complete or if the specimen or the documents do not meet the requirements, so that subsequent improvements are necessary.

We will inform you by interim notices of the state of processing, in particular if the expected date of completion stated at the beginning of the processing time cannot be met due to new findings.

A2.3 Testing criteria

Important evaluation criteria of the conformity tests are the stability of the measuring instruments with respect to environmental influences such as temperature, humidity, shocks and electromagnetic fields. Furthermore, the measuring instruments must be suitably protected from the falsification of measurement results due to operating errors or manipulation. This applies also to the software of computer-controlled devices. Ancillary devices and interfaces on measuring instruments are tested, among other things, for non-interaction. "Non-interacting" means that it is not possible to inadmissibly influence the measurement values obtained with a measuring instrument subject to mandatory verification.

A2.4 Recognition of test results

Tests can also be carried out by the manufacturer or an agency commissioned by the manufacturer and the test results can be used for the assessment if the testing laboratory involved meets certain requirements such as, for example, requirements for calibration and testing laboratories on the basis of DIN EN ISO/IEC 17025.

A2.5 Type-approval certificate under German law (national type approval)

A2.5.1 Requirements

Within the scope of the national type approval, it is investigated whether the instruments are likely to meet the requirements for correctness and reliability for the period of validity of verification. The type must comply with the basic requirements of the Verification Ordinance and fulfil the accepted rules of technology. Especially the PTB Testing Instructions and DIN standards are considered as accepted rules of technology.

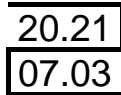
A measuring instrument type which deviates from these rules can, however, be admitted for verification if the same reliability is ensured in a different way. The deviating requirements will be laid down during the type approval test.

A2.5.2 Certificate

The national type approval usually has an **unlimited validity**. Deviating from the regular case, the validity of the type approval can have a limited validity if, for example, the final assessment of the type can be completed only after the measuring instruments have been tested under operating conditions. Limitation of the type approval in time means that the type approval is valid only for a certain period or begins or ends at a certain date. The measuring instruments which are already in use continue, however, to be considered as having been approved (Section 20 para. 2 EO).

Along with the type approval, PTB issues an **approval mark**. The manufacturer may apply the approval mark only to instruments which comply with the type approved.

Approval mark (example):



The approval mark is composed of a symbol in the shape of a stylised "Z" and the approval number with the indications of the Verification Ordinance on the measuring instrument category (20.21), the year of approval (07) and a serial number (03).

The Annex to the type approval certificate specifies the requirements which must be met by the measuring instruments of the approved type. Likewise, **limitations** are stated for the case in which novel technical developments are applied which are not included in the Verification Ordinance, for example, if the number of approved measuring instruments or the area of application of the measuring instruments are limited by PTB. After granting the approval, PTB may subject the measuring instruments which are already in operation to specific tests and define a shorter period of validity of verification. PTB can limit the validity of such an approval and, if applicable, later lift the limitation upon application.

In the annex, **conditions and obligations** are listed for the case in which the approval is bound to certain conditions, e.g. the application of a missing inscription or to the maintenance by a maintenance service at regular intervals.

The type approval is an administrative act resulting in a benefit and provides the holder of the type approval with an advantageous legal position on the basis of the Administrative Proceedings Law. Against the requirements, limitations, conditions etc. specified in the type approval certificate, remedies (protest, proceedings before an administrative court) can be taken.

A2.5.3 Section 22 Retaining and depositing of samples and records

PTB can require that samples and documents as well as - if applicable - the software documentation be kept and deposited (section 22 EO). It is the purpose of the keeping and depositing of samples and documents to ensure that samples and documents can later be compared with the manufactured instruments of the approved type.

A.2.6 EEC type approval

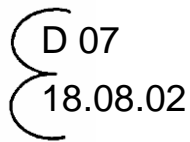
A2.6.1 Requirements

In the case of the EEC type approval, all requirements are contained in the corresponding EEC directive which has been fully transposed into the Verification Ordinance. Deviating or additional national requirements may not be placed on EEC-approved measuring instruments.

A2.6.2 Certificate

The EEC type approval has a **limited validity** of, in general, 10 years. The type approval is issued with an approval mark. The manufacturer may apply the **approval mark** only to instruments which comply with the type approved.

EEC approval mark (example):



The approval mark is composed of a symbol in the form of a stylised "ε" and the approval number, in the upper part with the letter "D" for Germany for PTB approvals and the year of approval (07); in the lower part with indications with regard to the measuring instrument category (18.08) and a serial number (02).

The Annex to the type approval certificate specifies the requirements which must be met by the measuring instruments of the approved type, as well as, if applicable, conditions and obligations.

Upon application, the approval can be prolonged by another 10 years when the type approved complies with the currently valid requirements of the EEC directive.

The type approval is a promotive administrative act. Against the requirements, limitations, conditions etc. specified in the type approval certificate, remedies (protest, proceedings before an administrative court) can be taken.

A2.6.3 Retaining and depositing of samples and records

Upon PTB's request, samples and documents may be retained or deposited to ensure a subsequent comparability of samples and documents with the produced instruments of the approved type (section 22 EO).

A2.7 EC type approval, EC type and design examination

A2.7.1 Requirements

For the EC type approval of non-automatic weighing instruments according to Directive 2009/23/EC (NAWI Directive) and the EC type or design examination for measuring instruments according to Directive 2004/22/EC (MID), the requirements stated in the corresponding directive which have been transposed into the Verification Ordinance must be met.

The EC directives NAWI and MID lay down, according to the principle of the "New Approach", only basic requirements on the measuring performance of the instruments. More precise technical requirements are laid down in the standards and international regulations. If the manufacturer applies the harmonised standards or normative documents (OIML) issued on the basis of these directives and made public in the EU Gazette, the notified body assumes, when assessing the conformity of the instrument, that the basic requirements are met. This is related to those parts of the harmonised standards or normative documents which contribute to the basic requirements stated in the directives to be met. This changes correspondingly when the manufacturer has applied these standards or normative documents only partially. The manufacturer may, however, make use of other solutions or, in the case of technical further developments, deviate from the accepted rules. The notified body must then assess whether the basic requirements are still met by the solution chosen by the manufacturer.

Non-automatic weighing instruments: basic requirements according to Annex I of the NAWI Directive, the harmonised standard is the DIN EN 45501.

MID measuring instruments: basic requirements according to Annex I and to the corresponding annex (e.g. MI-001); harmonised standards and normative documents (OIML) for measuring instruments, see Official Journal of the EU C47 of 20-02-2008, p. 21 and C162 of 14-07-2007, p. 13 (Standards), C269 of 04-11-2006, p. 1 (OIML).

A2.7.2 EC type approval certificate (NAWI Directive)

PTB, as a notified body, grants the applicant the EC type approval (NAWI Directive). The approval is limited to 10 years. The number of the type approval must be applied to each instrument.

Number of an EC type approval (example):

D07-09-001

The number is composed of the letter "D" for Germany, the year of issuing of the attestation (07), the number of the Annex of the Verification Ordinance for non-automatic weighing instruments (09), as well as a serial number (001).

The approval can be prolonged by another 10 years upon application if the type meets the currently valid requirements of the directive. In this case, PTB issues a revision of the type approval.

A2.7.3 EC type or design examination certificate (MID)

PTB, as the notified body No. 0102, issues to the manufacturer the EC type or design examination certificate. The EC certificates are limited to 10 years. Each certificate receives an unambiguous certificate number which must be applied to the measuring instrument.

Number of an EC type or design examination certificates (example):

DE-07-MI001-PTB001

The number contains the letters "DE" for Germany, the year of issuing of the certificate (07), the MID annex valid for this type of measuring instrument (MI001), the acronym PTB, as well as a serial number (001).

In the annex to the EC certificate, the requirements are laid down which must be met by the measuring instruments and, if applicable, the measures which ensure a uniform production of the measuring instruments.

The validity period of the EC type and design examination certificates can be prolonged by another 10 years upon application if the type or design meets the currently valid MID requirements.

A2.7.4 Basis for granting approval

EC type and design examination certificates are issued by PTB, as a notified body, under private law. There is no legal claim to these services. PTB's terms and conditions for conformity assessments, testing, measurement and calibration services (**AGB**) apply.

A3 Amendments of issued certificates

Approval owners or manufacturers are obliged to inform PTB about any subsequent modifications made to the approved type or design. Otherwise, the issued certificate can be withdrawn.

It is necessary to modify the type approval if these modifications and supplements may have an influence on the measurement results or the normal conditions of use of the measuring instrument. An amendment can, however, only be granted if the measuring instruments still meet the requirements which were valid at the date of issuance. After a considerable alteration of these provisions, a new certificate (type approval, EC type or design examination certificate) is generally necessary for a new type of design. PTB may modify or supplement only such certificates which it has issued itself.

The amendment is usually granted by means of a revision or a new version.

For MID instruments which received a national or an EEC type approval before October 30, 2006, a right of continuance is granted for the placing on the market of these instruments until October 30, 2016 at the latest. Alterations of the approvals are, however, no longer granted approval - except for those of formal nature. For further information on this topic, please consult the instruction sheet on the implementation of the MID / Application of the transitional regulation.

A4 Use of the rights and duties with regard to the issued certificate

A4.1 Transfer

A type approval or an EC type or design examination certificate can be transferred to third parties upon the application of the owner of the certificate. A declaration of approval is required by the original owner. In the case of a transfer, the original owner waives his rights and duties with regard to the issued certificate. If applicable a transfer of the stored samples and documents of the original owner to the new owner has to be declared by the new owner.

A4.2 Multiplication

On the following terms, we are able to conduct a simplified procedure for issuing a certificate on the basis of an existing certificate (previous: parallel approval):

- The types are technically identical.
- There is an agreement available by the owner of the existing certificate for the use of existent test and validation results of the applied procedure
- The owner of the existing certificate ensures that the new holder respectively the market surveillance authorities (who address the new holder) get an access to the technical documents of the measuring instruments

The applicant is exclusively responsible for questions regarding copyright of the type, respectively design or other judicial subjects (like legal protection of registered designs, patent law)

The use of test and validation results makes no change concerning the responsibility of the new holder, concerning accordance of the measuring instruments with the commitments in the certificate as well as compliance with statutory provisions under its own name signed measuring instruments.

The certificate holder assume all rights and duties of the issued certificates.

A4.3 Co-sellers

In the case of national and EEC type approvals, the holder of the approval rights may, upon application, allow other companies to sell the measuring instruments whose approval he holds under the name or make of these companies (section 19, para. 2, EO). The rights and duties related to the approval remain with the approval holder. The arrangement of distribution rights is a matter under private law between the holder of the approval rights and the co-seller.

A5 Withdrawal and revocation

PTB may withdraw or revoke the certificates issued if the reliability of the approved measuring instruments is not ensured or if it is impaired (Section 25a EO and clause 2.5 of Annex 9 EO) or if the preconditions for issuing a certificate are no longer given (Terms and Conditions of PTB).

Withdrawal means the annulment of an unlawful type approval with the effect that the approval ends at the date specified in the withdrawal notice. As a consequence, the measuring instruments in use may no longer be kept ready and used.

The same is valid for certificates which have been withdrawn pursuant to the terms and conditions of PTB.

Revocation means the annulment of a lawfully issued approval with an effect for the future and will be made if the reliability is impaired by an event occurring after the approval. The approval can also be revoked if the holder of the approval subsequently modifies design criteria of the measuring instruments which may influence the reliability, if he does not observe limitations as to content or conditions of the approval or if he does not meet conditions within the time specified. Measuring instruments in use continue, however, to be considered as having been approved.

The same is valid for certificates which have been declared invalid pursuant to the terms and conditions of PTB.

A6 Costs

PTB raises charges (fees and outlay)

- for type approvals of PTB (official acts) according to the amount of work arising and the hourly rates of *the Regulations Governing Charges for Approvals granted by PTB*¹⁰ including Type approvals for non automatic weighing instruments
- for certificates issued by PTB as a notified body, according to the amount of work arising and hourly rates of the *Regulations Governing Charges for Services Supplied by the PTB (KVONL)*¹¹ or in accordance with the fixed rates according to the KVONL.

Travelling and waiting times as well as above-average pertinent expenses can result in the fees being increased. Outlays will be charged separately.

Prior to starting the testing, PTB may ask for an advance payment to the amount of the costs which will probably arise. The issuing of the certificate and its notification can be made conditional on the payment of the entire costs.

If, after six months from the date of application, PTB has not yet received the complete test documents and if the applicant has not given sound reasons for the delay and if, as a result, the progress of the procedure is unforeseeable, PTB will reserve the right to discontinue the type approval procedure and invoice the applicant for the costs incurred until this date in accordance with the respective *Regulations Governing Charges* that apply in this special case.

Other technical services rendered by PTB to the applicant - as far as these are services which exceed a general minor consultancy service – are also invoiced in accordance with the amount of work arising. If these services are directly related to the application for type approval, they are invoiced together with the other costs in accordance with the respective *Regulations Governing Charges* that apply in this special case.

A7 Announcement

To inform the public, the certificates issued are published in an abridged version in the information bulletin of the PTB, "*PTB-Mitteilungen*". Modifications of the certificates, as well as withdrawals and annulments are published in the same way.

A8 Recognition of foreign type approvals

Measuring instruments which have been legally manufactured or placed on the market in another member state of the European Union, in Turkey or in another signatory state of the European Economic Area are treated equally, incl. tests and identifications, if these measuring instruments ensure a comparable level of consumer protection, competition and other existing subjects of protection for the public benefit (Section 80, EO). Manufacturers can apply for equivalence evaluation at PTB. PTB then publishes its decisions in the PTB information bulletin "*PTB-Mitteilungen*".

¹⁰ Sec 13a of the Verification Act in conjunction with the Regulations Governing Charges for Approvals granted by PTB according to sec § 14 Verification Act.

¹¹ Sec 7 of the UnitsTimeAct in conjunction with the KVONL

Annex B: QM recognition

Annex B deals with applications for the following certificates:

1. Recognition of a QM system according to Directive 2004/22/EC Annex H1 or H
2. Recognition of a QM system according to Directive 2004/22/EC Annex D or D1, E, E1

B1 Application

Please apply for QM recognition with the certifier in charge at PTB (see Annex C). We recommend that you inform yourself on the procedure and requirements as early as in the development phase of a measuring instrument category.

B1.1 Application form

For the application, please use the application form as well as the questionnaire for the preparation for a QM recognition (list of preliminary questions) of the certification body. You can also file your application in English. The forms can be downloaded from the Internet pages of the certification body (see "Services", "Certification Bodies").

PTB needs the following information for the formal processing of the applications:

- a) Name and address of the manufacturer (or his authorised representative);
- b) the envisaged procedure of conformity assessment (Annex D D1, E, E1, H or H1);
- c) the manufacturer's sites which are included in the QM system;
- d) the measuring instrument categories to which the QM system refers.

B1.2 Documents for the application

Please enclose the following documents to your application after contacting your certifier for preliminary questions:

- e) the quality manual;
- f) if applicable, copies of already existing QM certificates;
- g) a list of the documents on the QM system according to MID (Annex E, D, H, H1 clause 3.2 as well as Annex E1, D1 clause 5.2);
- h) a list of the measuring instrument categories for which an EC declaration of conformity is envisaged by the manufacturer within the scope of the QM recognition applied for (as far as available, with indications on the design and type examination certificate);
- i) copies of the design/type test certificates if these have not been issued by PTB;
- j) further descriptions of the QM measures for the individual measuring instrument categories which ensure compliance with the requirements of the MID.
- k) The signed **General Terms and Conditions of Certification of the PTB (AZB)**, available under: <http://www.ptb.de/en/org/zs/index.htm> „General Information for Customers”, AZB

B1.3 Application confirmation

We will send you an application confirmation to confirm the acceptance of your application; if necessary, it will contain a list of additional documents to be submitted.

The application can be processed only if all documents have been submitted and are available for the testing.

B2 QM assessment and issuing of the certificate

B2.1 General

When assessing the QM system of the manufacturer, it is checked whether the system ensures compliance of the measuring instruments with the type described in the EC type and design examination certificate (by procedures according to Annex D, E or H1) and with the corresponding requirements stated in the directive.

For this purpose, PTB carries out a product-specific audit of the quality assurance measures for the corresponding measuring instrument categories at the manufacturer's. If the manufacturer already has a certified QM system according to ISO 9001, the amount of work is reduced. (Note: certifications according to ISO 9001 are not part of the services offered by PTB). The audit comprises an assessment of the documents on the QM system and an in-situ assessment at the manufacturer's.

In Annex E or E1, the audit basically only comprises the final inspection; in Annex D or D1 manufacturing and the final inspection and in Annex H or H1, it also comprises the development of the measuring instrument categories. The complementary design examination stated in Annex H1 must also be carried out by PTB. If considerable parts of the development or manufacturing take place at different sites or at subcontractors', these are also included in the audit.

In order to ensure that the manufacturer fulfils his obligations with regard to the recognised QM system and, if necessary, implements the required corrective actions, the notified body carries out surveillance audits at regular intervals.

B2.2 Processing time

It is PTB's endeavour to complete the application for QM recognition within 3 months.

As experience has shown, delays will have to be expected if, for example, the documentation is not complete or if EC type or design examination certificates are not yet available for this type of design.

We will inform you by interim notices on the state of processing, in particular if the expected date of completion stated at the beginning of the processing time cannot be met due to new findings.

B2.3 Certificate

After the type evaluation has been successfully completed, PTB, as the notified body 0102, issues to the applicant a "Certificate on the Recognition of the Quality Management System according to Directive 2004/22/EC, Annex D" or the others. The certificate is provided with an unambiguous registration number. This number is **not** to be applied to the measuring instrument but should be included in the manufacturer's declaration of conformity.

The recognition is generally valid for a period of 3 years and can then be re-confirmed. During this period of time, the QM system is subject to surveillance and, if necessary, unannounced control visits by the notified body.

B2.4 Re-recognition

The QM recognition ends when its period of validity expires. If the conformity assessment is furthermore to be carried out on the basis of quality assurance, PTB can perform the re-recognition of the QM system. In this case, a new certificate is issued.

B3 Modifications of issued certificates

The certificate holder or the manufacturer has to inform PTB about any subsequent modifications of the recognised QM system. If he fails to do so, the recognition can be withdrawn. In the case of modifications on a recognised QM system, PTB decides whether a new assessment is necessary. This can be the case, e.g., if the production site, the test procedures or the production processes for the measuring instruments change or if the extent of

the recognition is to be extended to further measuring instrument categories. In the case of modifications of the EC type or design examination certificate, a modification of the QM recognition is not necessarily required.

The modification of a QM recognition is issued through a new annex to the certificate in which the **complete** scope is re-determined.

B4 Suspension, restriction and revocation

The QM recognitions issued by PTB can be suspended, restricted, withdrawn or declared as invalid by the PTB if it turns out subsequently that the conditions for granting the certificate are not or no longer fulfilled by the manufacturer and that appropriate corrective measures have not been applied.

B5 Costs

QM recognition is a service rendered by PTB under private law.

For certificates on QM recognition, PTB raises charges (fees and outlay) according to the amount of work arising and the hourly rate of the *Regulations Governing Charges for Services Supplied by the PTB (KVONL)*¹² or in accordance with the fixed rates according to the KVONL. Outlays will be charged separately.

Prior to starting the testing, PTB may ask for an advance payment to the amount of the costs which will probably arise. The issuing of the certificate and its notification can be made conditional on the payment of the entire costs.

If, after six months from the date of application, PTB has not yet received the complete documents, and if the applicant has not given sound reasons for the delay and if, as a result, the progress of the procedure is unforeseeable, PTB will reserve the right to discontinue the type approval procedure and invoice the applicant for the costs having arisen until that date in accordance with the respective *Regulations Governing Charges* that apply in this special case.

B6 Announcement

To inform the public, the QM recognitions as well as their modifications or withdrawals are published in an abridged version in the information bulletin of PTB ("*PTB-Mitteilungen*").

¹² Section 7 of the UnitsTimeAct in conjunction with the KVONL.