Implementation of MID and NAWID

Notification of MID and NAWID Conformity Assessment Bodies

Physikalisch-Technische Bundesanstalt, Germany



Brief introduction





Dr. Harry Stolz

Head of the certification body

Head of certification sector "Measuring Instruments Directive"

Responsible for all certification systems at PTB. Expert in legal metrology, accreditation in metrology, international technical cooperation in metrology



MID

= Measuring Instruments Directive

(Directive 2004/22/EC)

80 pages + 1000 pages (WELMEC guides)

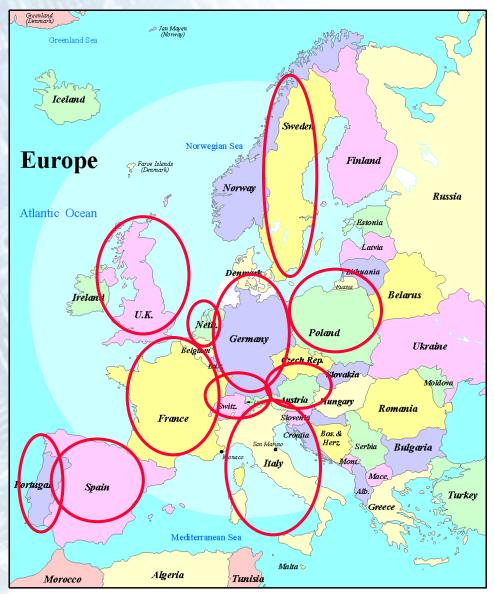
NAWID

= Non-Automatic Weighing Instruments Directive

(Directive 2009/23/EC, formerly 90/384/EC)

22 pages + 200 pages (WELMEC guides)





before 1971:

only national type approvals

costs time and money

 sometimes different requirements

 time to place instruments on the market relatively long



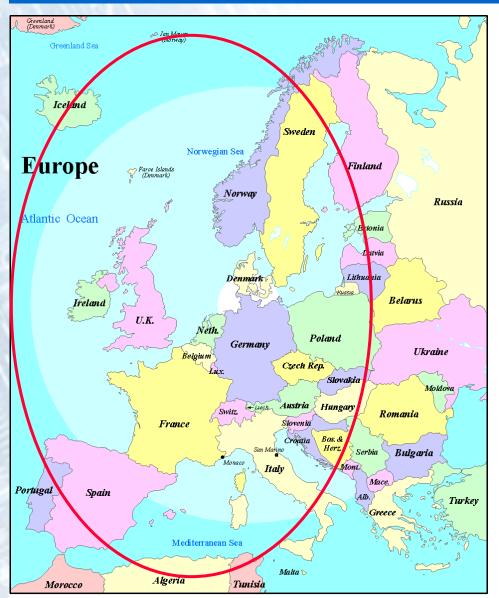


Non-automatic weighing instruments (NAWID)

- since 1990 (1990/384/EC) for different NAWIs
- more or less "New Approach"-direct.
- European type approv.





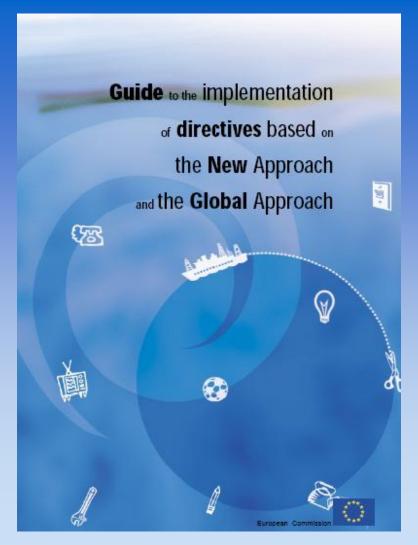


Measuring Instruments Directive (MID)

- since 2004 (2004/22/EC) for 10 meas. instruments
- based on the "New Approach"
- conformity assessment (modules)







"blue guide" (1999):



- how to place goods in the EC-market and how to put them into use
- responsibilities (manufacturer, user ...)
- EC declaration of conformity (CE marking)
- notified bodies
- market surveillance



New Approach principles:

- Legislation is limited to essential requirements.
- Only products fulfilling the essential requirements may be placed on the market and put into use.
- Harmonised standards, which have been published in the Official EU-Journal and which have been transposed into national standards, are presumed to be conform to the corresponding essential requirements.







New Approach principles:

- Application of harmonised standards or other technical specifications remains voluntary, and manufacturers are free to choose any technical solution that provides compliance with the essential requirements.
- Manufacturers may choose between different conformity assessment procedures provided for in the corresponding directive ("Global Approach").







<u>Directive</u> of the European Parliament and of the Council on <u>Measuring Instruments</u>

relevant for 31 European countries (2004/22/EC)

Measuring Instruments Directive = MID

30.4.2004

EN

Official Journal of the European Union

L 135/1

I

(Acts whose publication is obligatory)

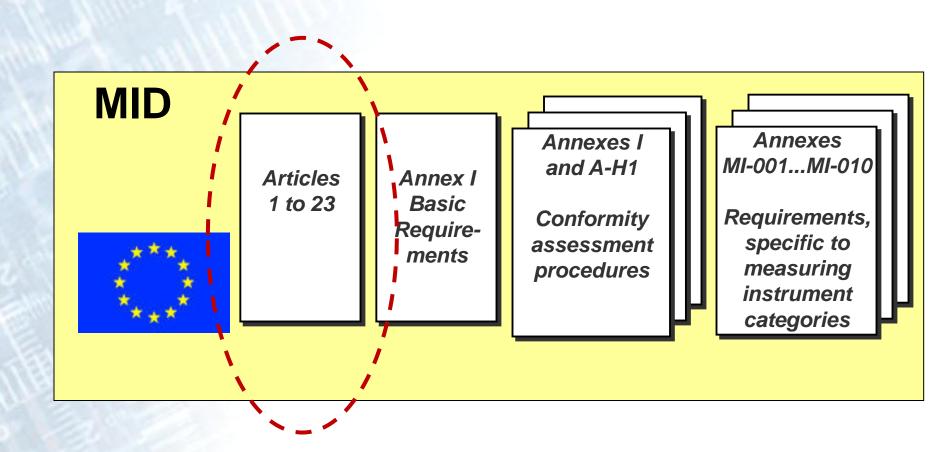
DIRECTIVE 2004/22/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 31 March 2004

on measuring instruments

(Text with EEA relevance)









Articles

regulating the procedures:

- Instruments covered,
- Definitions,
- Procedures for implementation, obligations, regulations,
- Criteria to be satisfied by the notified bodies,
- Necessary technical documentation from manufacturer,
- Member states obligations to perform market surveillance
- Safeguard clause in the case of non conformity,
- Changes and further development of the MID





MI-001 Water Meters

MI-002 Gas Meters and Volume Conversion Devices

MI-003 Active Electrical Energy Meters

MI-004 Heat Meters

(MI-001 to MI-004: for utility measuring purposes)

MI-005 Measuring Systems for the Measurement of

Quantities of Liquids other than Water

MI-006 Automatic Weighing Instruments

MI-007 Taximeters

MI-008 Material Measures (length, capacity measure)

MI-009 Dimensional Measuring Instruments (e.g. area)

MI-010 Exhaust Gas Analysers



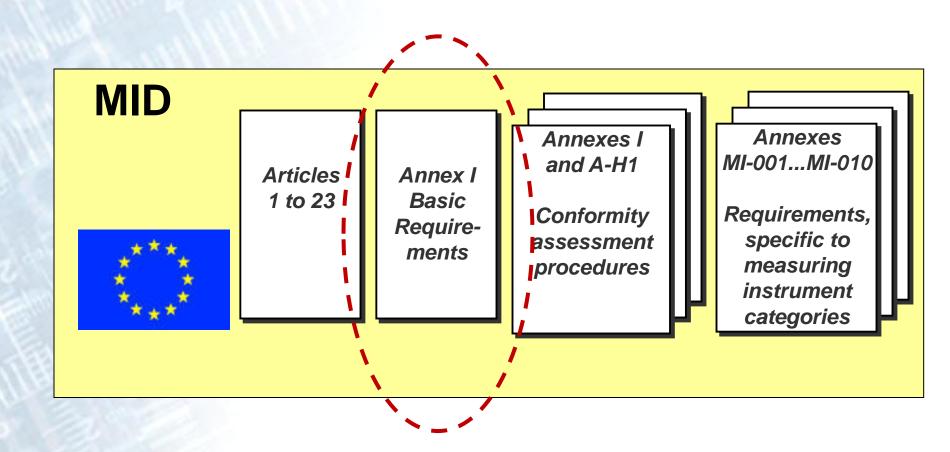


Basic Principle:

Regulations for legally controlled instruments are limited until "placing on the market" and/or "putting into use"

- Member states remain responsible for their legal metrological control (choice of controlled instruments, market surveillance), but
- National metrological control shall not lead to barriers for free movement of measuring instruments and
- Directives have to be implemented into national legislation.





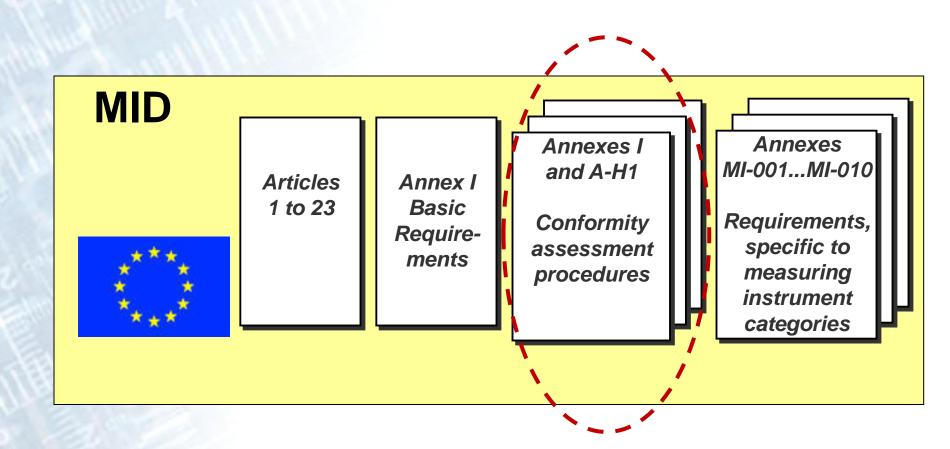




Essential Requirements: All instruments (Annex I)

- → Correct measurement: maximum permissible errors, durability
- → Influence quantities: mechanic, climatic, electromagnetic
- → Suitability for use, reproducibility
- → Verifiability: Metrolog. relevant parts, also for instruments in use
- → Additional functionalities, not under legal control
- → Protection against corruption (Hard- and Software)
- → Easy identification of metrological relevant Hard- and Software
- → Information to accompany the instruments
- → Indication of the result: (Metrologically controlled display for the consumer as the basis of the price to pay)
- → Further processing of data to conclude trading transaction





German verification act under revision



placing on the market and putting into use

use

Old national system:

public authority

 type approval (homologation)

verification authorities

2. initial verification

3. subsequent verification

New system (MID/NAWID):

manufacturer (+ notified body)

- conformity assessment (design phase)
- conformity to type

market surveillance by public authority

verification authorities

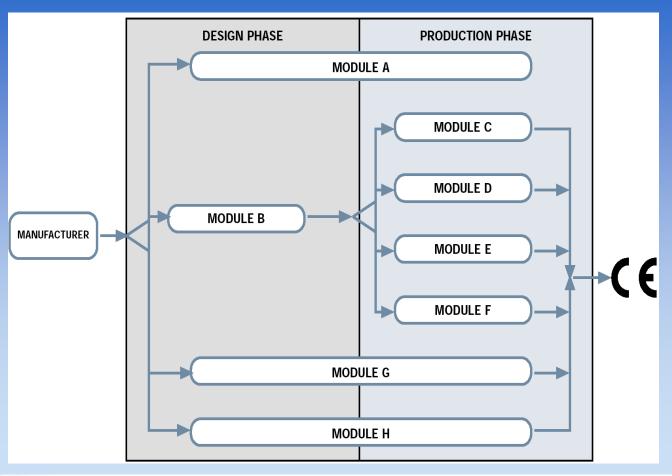
3. subsequent verification

user surveillance by public authority





Simplified flow chart of conformity assessment procedures (Global Approach)



("Blue Guide": www.newapproach.org)

Conformity assessment modules

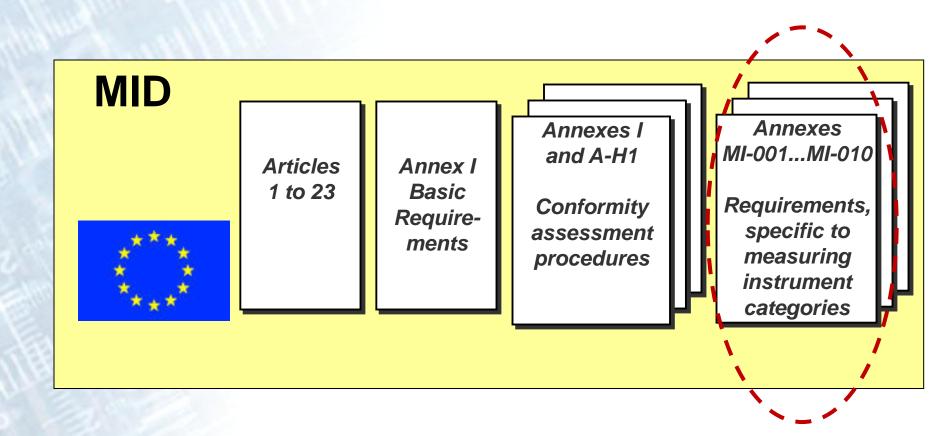




Ticket for the EC-Market since 30th October 2006:

- C = Conformity to applicable technical harmonisation Directives
 - **M** = Conformity to the legal metrology Directive 2004/22/EC
 - 13 = Year of affixing the CE- and the metrology marking
 - 0102 = Identification no. of the notified body, responsible for the conformity assessment procedure for 'placing on the market' and/or 'putting into use'









Instrument specific Essential Requirements

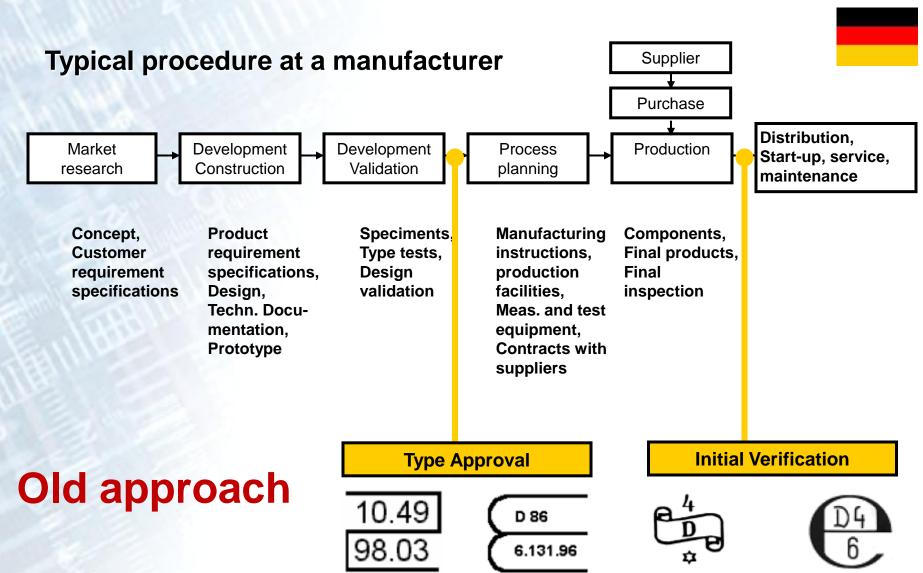
(Annexes MI-001 to MI-010)

- → Rated operating conditions (climatic, mechan., electromagn.)
- → Maximum permissible Errors (MPE) at rated operating cond.
- → Permissible effects of disturbances
- → Indication of the result
- → Allowed Conformity Assessment Procedures

If applicable:

- → Accuracy classes
- Conditions for putting into use
- → Suitability / Durability
- → Requirements for sub assemblies with conformity assessment

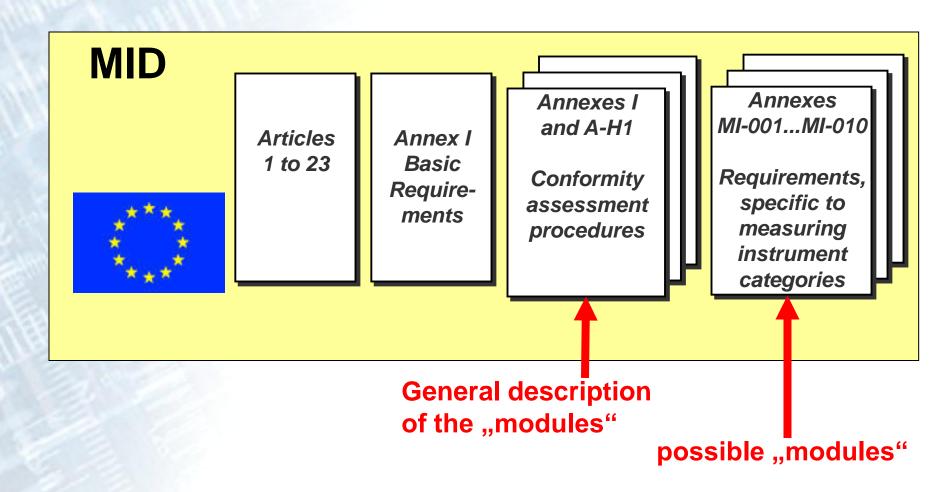






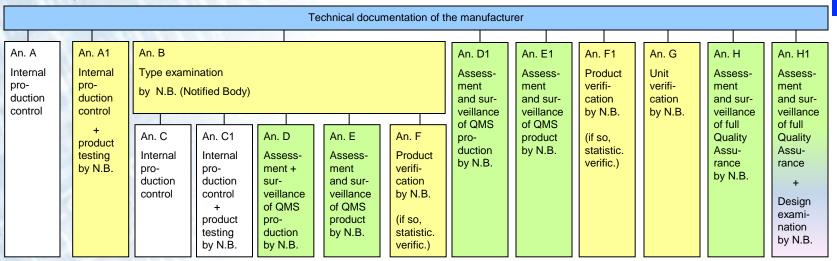
Structure of the Measuring Instruments Directive







Conformity assessment modules



| •MI-001, Water meters: | B+D, B+F, H1 |
|------------------------|--------------|
| m cor, trater metere. | 5.5,5.1,111 |

•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 continous and dynamic measurement B+D, B+F, G, H1

of quantities of liquids other than water

•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 SW: 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

A1, B+D, B+E, D1, E1, F1, H

•MI-009, Dimensional measuring instruments mechanical or electromechanical: B+D, B+E, B+F, D1, E1, F1, G, H, H1

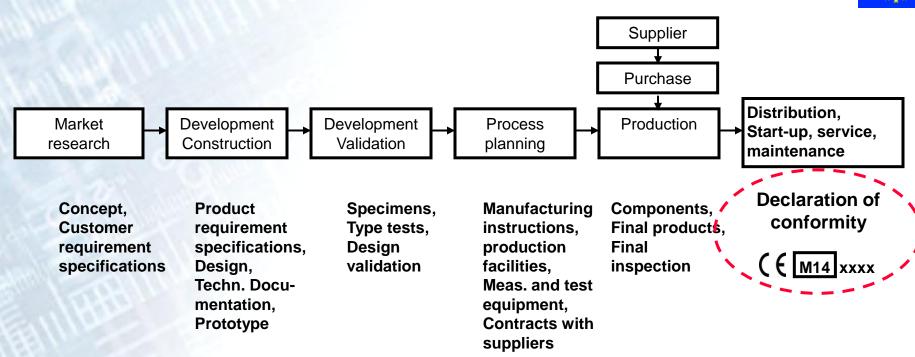
electronic or with SW: B+D, B+F, G, H1

•MI-010, Exhaust gas analysers B+D, B+F, H1



Conformity assessment modules





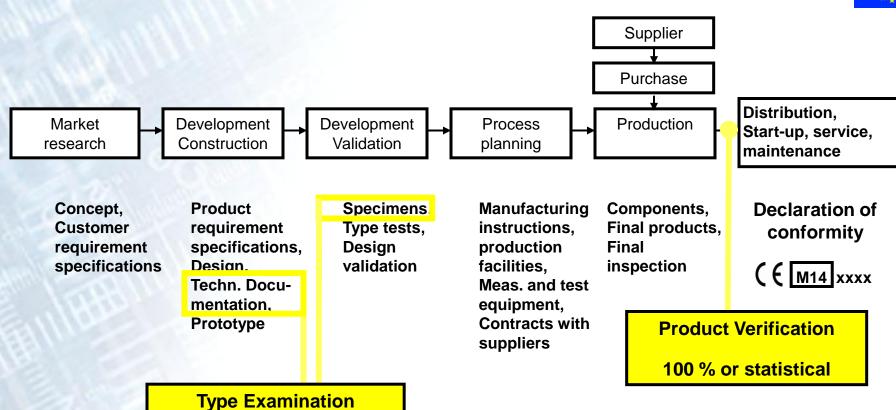
Module A: Conformity Declaration on base of internal production control of manufacturer (without notified body)

Not scheduled for MID so far!!!



Conformity assessment modules



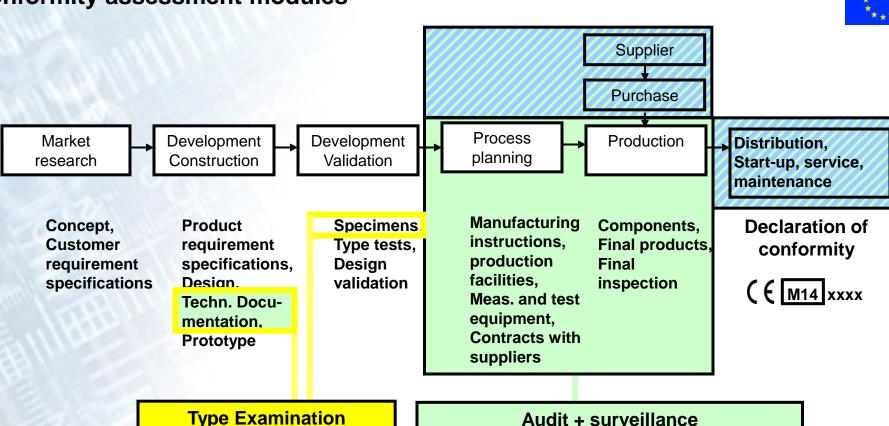


Modules B+F: Type Examination (B) and Product Verification (F)

Applicable for small batch production of instruments MI-001 bis MI-007, MI-009, MI-010 (corresponds to former type approval and initial verification)



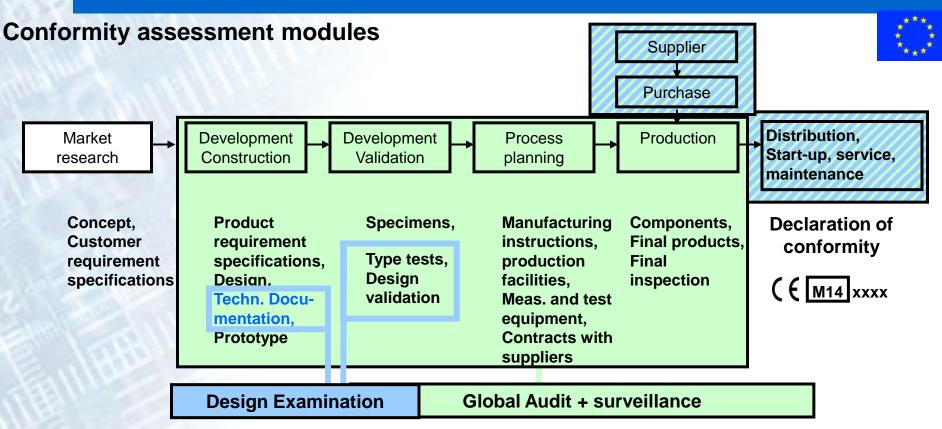
Conformity assessment modules



Modules B+D: Type examination (B) and approval of quality system for production (D) MI-001...MI-010

Applicable for large batch production with an existing ISO 9001-certificate





Module H1: Approval of quality management system for development and production + Design examination

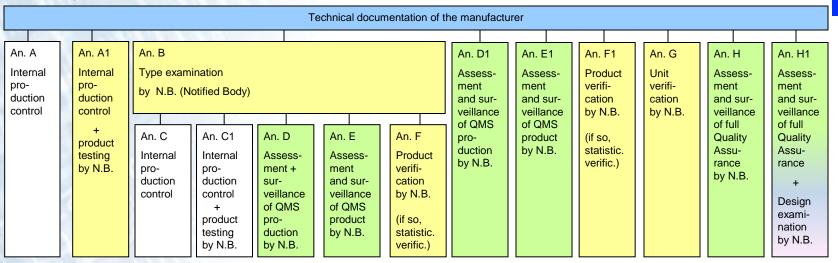
MI-001...MI-007, MI-009, MI-010

Applicable for manufacturers with own type test equipment and ISO 9001-certificate

30



Conformity assessment modules



| •MI-001, Water meters: | B+D, B+F, H1 |
|------------------------|--------------|
| | |

 MI-002. Gas meters and volume conversion devices B+D, B+F, H1

B+D, B+F, H1 •MI-003, Active electrical energy meters

B+D. B+F. H1 MI-004. Heat meters

B+D, B+F, G, H1 •MI-005, Measuring systems for the continous and dynamic measurement

of quantities of liquids other than water

•MI-006, Automatic weighing instruments B+D, B+E, B+F, D1, F1, G, H1 mechanical systems: B+D, B+E, B+F, G, H1 electromechanical systems:

> electronic systems or systems containing SW: B+D, B+F, G, H1

MI-007, Taximeters B+D, B+F, H1

I – Material measure of length B+D, D1, F1, G, H MI-008, Material measures

II - Capacity serving measures A1, B+D, B+E, D1, E1, F1, H

•MI-009, Dimensional measuring instruments 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

B+D. B+F. H1 •MI-010, Exhaust gas analysers

Revision of European "New Approch"



Some bad experiences with "New Approach":



- small and medium enterprises are more or less producing for a local market (not european-wide)
- market surveillance doesn't work in the EC (no concepts, no harmonisation)
- accreditation procedures are very different in the different member states (e.g. too many accreditation bodies)

Revision of new approach: New legal framework 2008 (NLF)



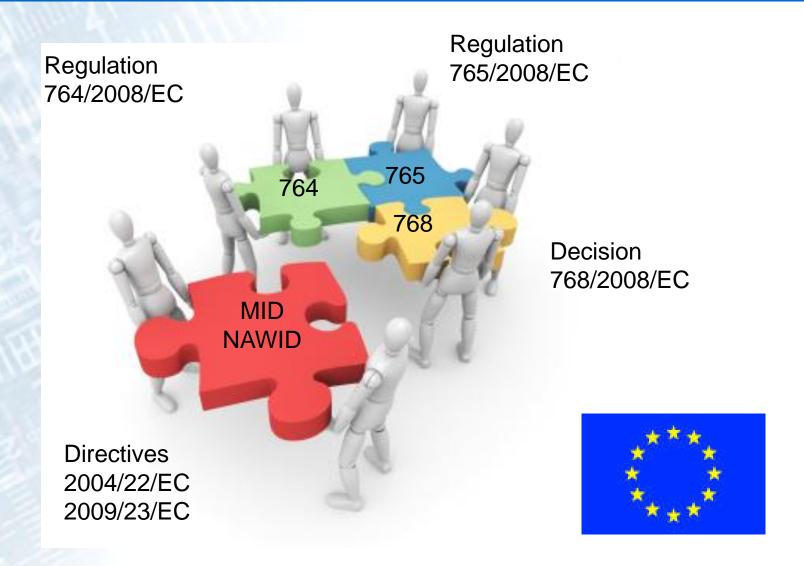
Regulation EC 764/2008 non-harmonised products Decision EC 768/2008 harmonised products



Regulation EC 765/2008 market surveillance

MID + NAWID + European legislation





Decision 768/2008/EC

EN



"New Legal Framework" (Decision 768/2008/EC):

Official Journal of the European Union



13.8.2008

DECISIONS ADOPTED JOINTLY BY THE EUROPEAN PARLIAMENT AND THE COUNCIL

DECISION No 768/2008/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 July 2008

on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC

(Text with EEA relevance)

ANNEX I

REFERENCE PROVISIONS FOR COMMUNITY HARMONISATION LEGISLATION FOR PRODUCTS

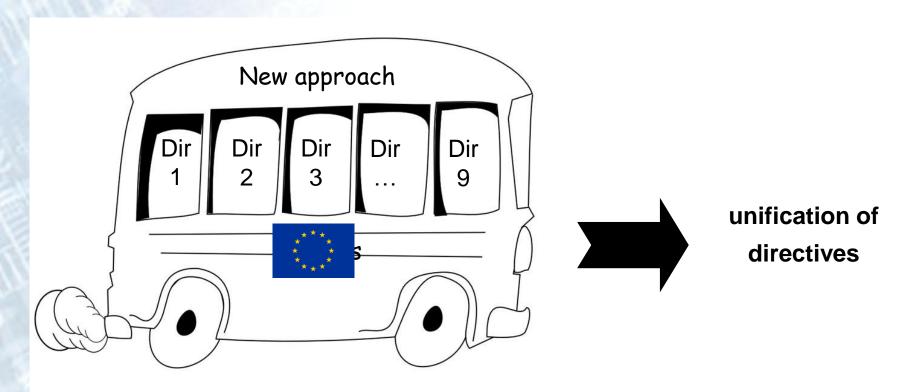
13. 'conformity assessment body' shall mean a body that performs conformity assessment activities including calibration, testing, certification and inspection;

L 218/82



Consequences of the "New legal framework":

revision of european guide lines ("OMNIBUS-procedure")





to make it easy for everyone





Consequences of the "New legal framework":

revision of european guide lines ("OMNIBUS-procedure")



New NAWID

Non-automatic

weighing instruments

Directive 2014/xx/EC



many changes!



New MID

Measuring Instruments

Directive 2014/xx/EC



only some changes!

⇒ process finished in March/April 2014





Consequences of the "New legal framework":

Non-automatic
weighing instruments
(NAWID)

Measuring Instruments
Directive (MID)





- ⇒ same definitions of e. g. "manufacturer", "importer" etc.
- ⇒ same obligation for economic operators
- **⇒** same conformity assessment modules
- ⇒New requirements for notified bodies





Requirements relating to notified bodies

- 1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.
- A conformity assessment body shall be established under national law and have legal personality.
- 3. A conformity assessment body shall be a third-party body independent of the organisation or the product it assesses. A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of products which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.





Requirements relating to notified bodies

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products which they assess, nor the authorised representative of any of those parties. This shall not preclude the use of assessed products that are necessary for the operations of the conformity assessment body or the use of such products for personal purposes.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those products, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.





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Requirements relating to notified bodies

..

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.



Requirements relating to notified bodies

. . .

- 6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by the legislation and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility. At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:
 - (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
 - (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;

....





Requirements relating to notified bodies

. .

- 7. The personnel responsible for carrying out conformity assessment activities shall have the following:
 - (a) sound technical and vocational training covering all the conformity
 assessment activities in relation to which the conformity assessment body
 has been notified;
 - (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
 - (c) appropriate knowledge and understanding of the essential requirements, of the applicable harmonised standards and of the relevant provisions of Community harmonisation legislation and of its implementing regulations;
 - (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.



Requirements relating to notified bodies

. . .

- 8. The impartiality of the conformity assessment bodies, their top level management and of the assessment personnel shall be guaranteed. The remuneration of the top level management and assessment personnel of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.
- Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.





Requirements relating to notified bodies

. . .

- 10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under the legislation or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.
- 11. Conformity assessment bodies shall participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Community harmonisation legislation and apply as general guidance the administrative decisions and documents produced as a result of the work of that group.





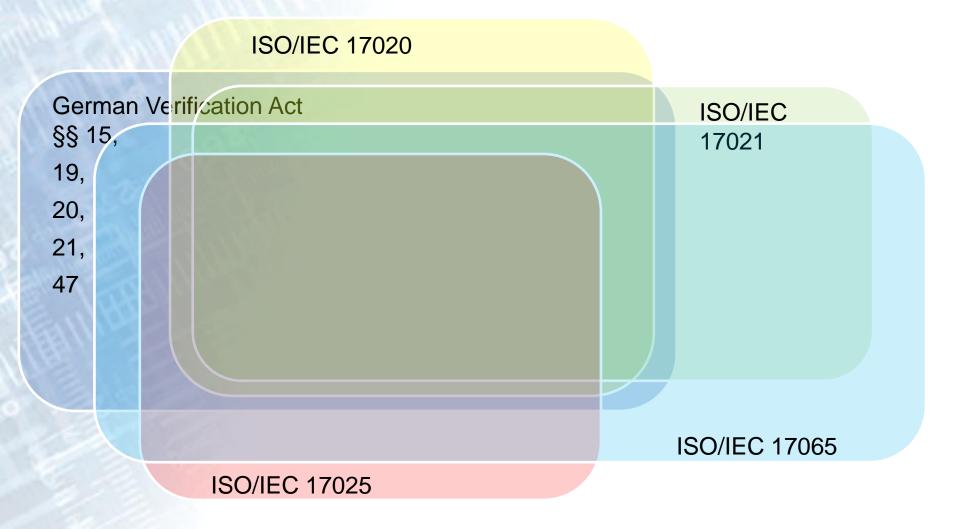
Presumption of conformity of competence of notified bodies

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union it shall be presumed to comply with the requirements set out in Article [R17] in so far as the applicable harmonised standards cover those requirements.

Respective conformity assessment standards:

- ISO/IEC 17065 (->product certification),
- ISO/IEC 17025 (->testing),
- ISO/IEC 17020 (->inspection),
- ISO/IEC 17021 (->management system certification)

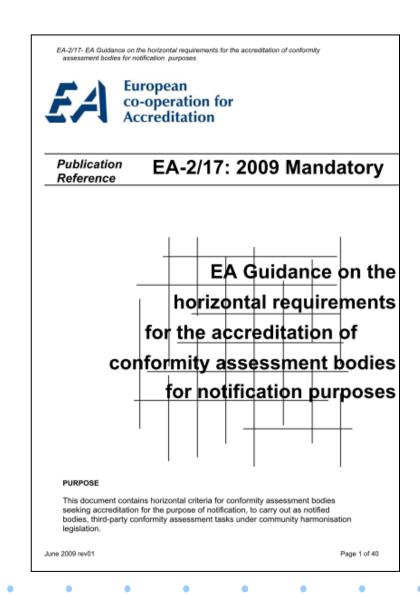
Problem: Standards do not cover legal requirements



Accreditation for notification purposes



Detailed information ->

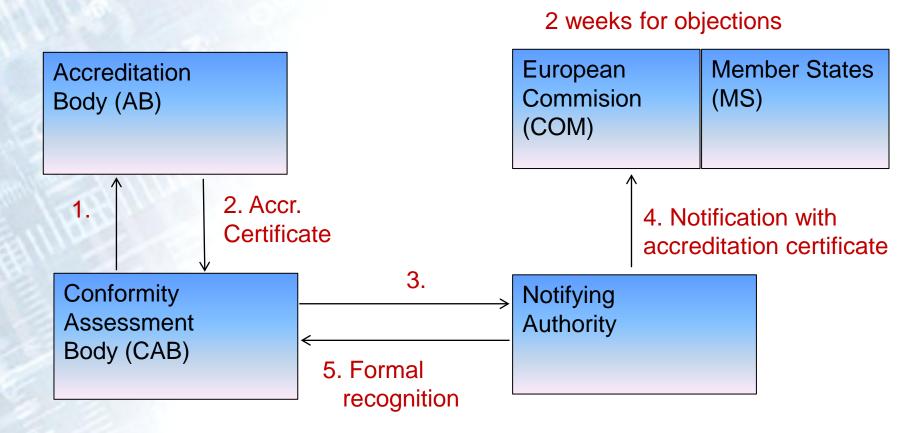


- Conformity assessement body notification procedure according to the new NAWID and MID
- Accreditation and the alternative procedure

Notification of Conformity Assessment Bodies



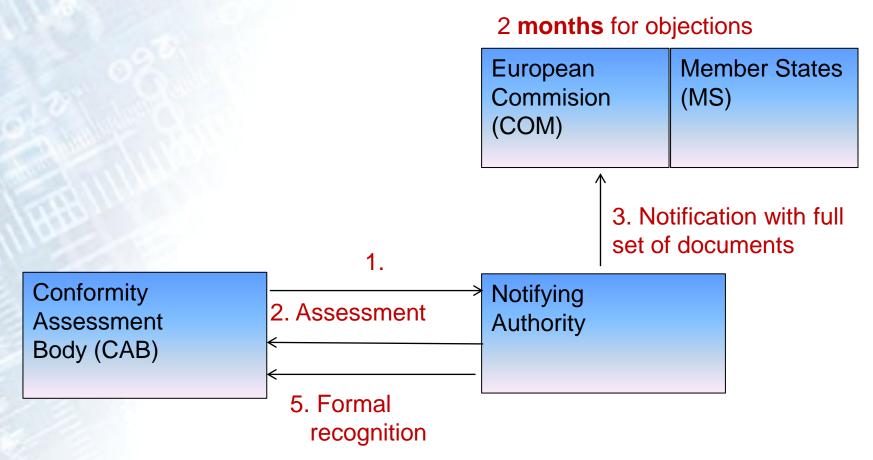
Typical Procedure using accreditation



Notification of Conformity Assessment Bodies



Typical Procedure without accreditation





Notification procedure

- Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article [R17].
- 2. They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.
- 3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and product or products concerned and the relevant attestation of competence.



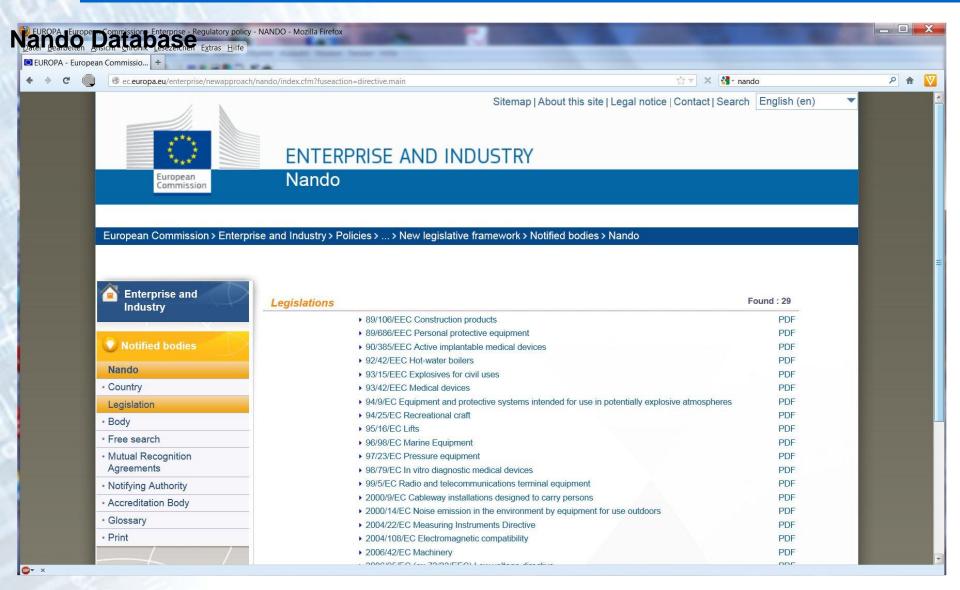
Notification procedure

. . .

- 4. Where a notification is not based on an accreditation certificate as referred to in Article [R22(2)], the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article [R17].
- 5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used. Only such a body shall be considered a notified body.
- 6. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.

Notification of Conformity Assessment Bodies





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Decision 768/2008/EC Article R14 Notifying authorities

Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with the provisions.

. . . .

Requirements relating to notifying authorities

- 1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.
- 2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.
- 3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.
- 4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.
- 5. A notifying authority shall safeguard the confidentiality of the information it obtains.
- 6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

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- Measuring Instruments attributed to legal metrology area.
- Principles of selection by government authorities

Definitions



2 different areas of German Metrological Infrastructure

Industrial Metrology

Voluntary Area

Principle:

Conformity assessment of measuring instruments by user of instrument

Basis:

Internal measurement control system (ISO 9001, ISO 10012)

Most important activities:

Calibration

Infrastructure: PTB, DAkkS, DKD

Legal Metrology

Legally Controlled Area

Principle:

Conformity assessment of measuring instruments by state / state controlled institutes

Basis:

Legal requirements for measuring instruments for specific applications

Most important activities:

Type examination, **Verification**

Infrastructure:

PTB, Notified Bodies, Verification Offices, approved testing laboratories

Protection in legal metrology





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Protection in legal metrology

fair trade



official measurements



environmental protection



safety at work



fiscal fairness



Calibration vs. Verification



criteria for instruments to be covered by verification:

- if there is substantial economic relevance in Germany
- to establish a fair trade, when one of the trading partners is not able to judge the correctness of the measurement (= to protect a consumer) or is absent
- for official measurements (e.g. speed meters, breath alcohol analyzers, sound level meters, ...),
 which could be submitted to a court

Calibration vs. Verification



criteria for instruments to be covered by calibration:

- if there is an interest of the owner of the instrument to get precise measured values
- if there is no interest to manipulate measured values
- if the instrument is not used for official measurements
- if the results are not expected to be taken to court

Links

Further Information

New approach of EU:

http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/new-legislative-framework/

Notified Bodies (NANDO-Database):

http://ec.europa.eu/enterprise/newapproach/nando/

EU-Webpage Measuring Instruments:

http://ec.europa.eu/enterprise/sectors/legal-metrology-and-prepack/measuring-instruments/index_en.htm

WELMEC:

http://www.welmec.org