Activities of PTB in the field of legal metrology

European requirements to measuring instruments
New German measurement and verification law
Revision of EN 45501

Dr.-Ing. Dorothea Knopf, department “Mass”
JMIF, 18 February 2014
European Single Market for Goods

- Aim is to create a **user-friendly environment for business and consumers.**
  - High standards of safety for consumers and protection of the environment
  - Remove existing barriers to trade and avoid the creation of new ones (according to WTO-Agreement on Technical Barriers to Trade) – design, implementation and improvement of regulatory policy
- Notification procedure following directive 98/34/EC
  - transparent, simple and consistent rules which offer legal certainty and clarity for business and consumers

http://ec.europa.eu/enterprise/policies/single-market-goods

Dr.-Ing. Dorothea Knopf, Seminar at JMiF, 18 February 2014
In general, the legislative architecture of the internal market for industrial products is established on the following building blocks:

- Safety (or environmental protection, or other public interest protection) **requirements**
- Voluntary or compulsory technical specifications to which products should conform. **Standards** are voluntary technical specifications.

http://ec.europa.eu/enterprise/policies/single-market-goods
Harmonises Standards and other Documents

• Conformity of an instrument with the general requirements is presumed if an instrument is in line with
  – European harmonised standards – EN 45501
  – Normative documents, as far as they were declared to be applicable by the European Commission
    • Usually in the “Official Journal” with cross-reference Tables

• Additional guidance documents for measuring instruments
  – developed by WELMEC and agreed by Commissions working group “Measuring Instruments”
  – Documents are not legally binding – but represent a reference for coherent application of the involved directives.

• “Blue-guide” of the Commission (just in revision)
In general, the legislative architecture of the internal market for industrial products is established on the following building blocks:

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- Specific procedures to follow in order to demonstrate that the technical specifications satisfy the essential requirements (for example that a product is safe). This process is known as **conformity assessment**.

http://ec.europa.eu/enterprise/policies/single-market-goods
Conformity assessment procedures

• Demonstrate that an instrument conforms to the essential requirements.

• Manufacturer may choose between different procedures.

• Procedures are composed of one or more modules.

• Modules are related to:
  – Design phase of the product
  – Production phase

• EC declaration of conformity
  – Is part of each assessment procedure
  – Contains all relevant information (legislation, manufacturer, notified bodies, the product itself, reference to standards etc.).

• Even if more that one legislation is valid only one declaration of conformity is established.
EU internal market for products

In general, the legislative architecture of the internal market for industrial products is established on the following building blocks:

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- Specific procedures to follow in order to demonstrate that the technical specifications satisfy the essential requirements (for example that a product is safe). This process is known as **conformity assessment**.
- 3rd parties (so-called **conformity assessment bodies**) which are involved in conformity assessment procedures for complex products and certify that the technical specifications meet the safety requirements.
Conformity Assessment Bodies - Notified Bodies

- Provide services for conformity assessment
- Are free to offer their services within their scope of notification to any economic operator established either inside or outside the EU.
- Manufacturers are free to choose any notified body (designated for the conformity assessment in question).
- Member states inform the European Commission about the designation of laboratories/institutions (published in the NANDO data base via internet).
- Strict requirements for notification – e.g. technical competence, independency, impartiality, transparency
EU internal market for products

- Other organisations which in turn certify that conformity assessment bodies are properly qualified to perform their activities. This process is known as **accreditation**.
Accreditation as tool of public control

• Shall ensure that conformity assessment bodies have the technical capacity to perform their tasks adequately.
• Aims to increase trust.
• Harmonised standards and documents of the regional and international accreditation organisations define competence criteria.
• Main principles in the EU are:
  – One accreditation body per member country
  – Accreditation is a public sector activity
  – Not-for-profit activity
  – Stakeholder representation is ensured
  – Preferred means in the appointment of notified bodies
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**Market surveillance** activities performed by the Member States.

Controls of products coming from outside the EU performed by the customs authorities in the Member States.
Market Surveillance

• Safer products and more fair play in the internal market
• Tasks:
  – Identify products not in line with the respective European legislation
  – Stop circulation of such products
  – Inform and co-operate with other market surveillance authorities
• Clear obligations – necessary powers, resources and knowledge
• Information about the national authorities and their market surveillance programs is available at EU-web-site.
• Cooperation at EU level:
  – RAPEX – Rapid Information Exchange System
  – ICSMS – Information about Safeguard procedures
EU internal market for products

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- **Market surveillance** activities performed by the Member States.
- Controls of products coming from outside the EU performed by the customs authorities in the Member States.
- For most, but not all products, **manufacturers** must label the product with a CE marking by which they declare on their sole **responsibility** that the products comply with all the Union legislative requirements applicable to the product. **CE marking** applies to products ranging from electrical equipment to toys and from civil explosives to medical devices.

http://ec.europa.eu/enterprise/policies/single-market-goods
CE Marking

• Mark states:
  – Product meets EU safety, health and environmental requirements
  – Product was assessed before placed on the market

• Additional specific marks for specific legislation
  – For measuring instruments

• Manufacturer is responsible for affixing the markings and placing on the market.

• Information for economic operators and consumers at
c.europa.eu/enterprise/policies/single-market-goods/cemarking
EU internal market for products

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European legislation covers placing on the market only. Legal verification in use has to be organised by national legislation.

http://ec.europa.eu/enterprise/policies/single-market-goods

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New Legislative Framework of the EU

- Improve market surveillance rules – protection of users and professionals from unsafe products
- Boost the quality of conformity assessment – stronger clearer rules on the requirements for the notification of conformity assessment bodies including the increased use of accreditation
- CE marking – clarification of the meaning, protection as a trade mark to allow legal actions against abuse
- Toolbox of measures for use in future legislation – more consistent and easier to implement sectoral legislation in future
New Legislative Framework of the EU

• Regulation 765/2008 – requirements for accreditation and market surveillance

• Decision 768/2008/EC – common framework for the marketing of products – “Omnibus”
  – Basis for the harmonization of nine European Directives (Alignment Package of 2011)
  – MID (2004/22/EU) – Automatic Weighing Instruments according to Annex MI-006

• Regulation 764/2008 – “new mutual recognition regulation” relating to national technical rules
Status Quo in German legal metrology

General Requirements

German Verification Law

Verification Regulation (General)

Annexes 1 to 23 (Specific)

Specific Requirements e.g. annexes MI001-010

- EEC Directives (old)
Responsibilities in the old Verification Legislation

Vollversammlung für das Eichwesen (Plenary meeting of German legal Metrology)

- Type Approval
- Primary Verification
- Subsequent Verification

National Metrology Institute (PTB)

Federal verification authorities

Conformity Assessment by notified bodies
Conformity Declaration by manufacturer
Market Surveillance

Federal Verification Authorities
### New German Verification legislation

<table>
<thead>
<tr>
<th>Measuring and Verification Act (MEG)</th>
<th>Measuring and Verification Regulation (MEV)</th>
<th>Committee of Rules state-of-the-art of Technology in Germany</th>
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<tbody>
<tr>
<td>• Rough list of instruments</td>
<td>• Requirements of MID; general and specific</td>
<td>• Rules and technical Specifications</td>
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<td>• Requirements of NAWID</td>
<td>• Requirements of MID; general and specific</td>
<td>• Procedures of conformity assessment</td>
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<td>• Modules of Conformity Assessment</td>
<td>• Modules of Conformity Assessment</td>
<td>• Obligations of the user of an instrument</td>
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<td></td>
<td></td>
<td>• Consists of PTB, federal authorities, conformity assessment bodies, manufacturer organisations, user organisations</td>
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<td>• Publishes References of the determined Rules and Specifications officially</td>
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**Physikalisch-Technische Bundesanstalt**

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Requirements on Instruments in Legal Metrology

- General requirements as stated in the German Verification Act:
  - Requirements defined in the Verification Regulation (MID, NAWID)
  - Instruments have to comply with the state-of-the-art of technology

- Conformity of an instrument with the general requirements is presumed if an instrument is in line with
  - European harmonised standards
  - Normative documents, as far as they were declared to be applicable by the European Commission
  - Rules and Specifications determined by the German Committee of Rules with the respective references published officially
Requirements concerning Software

- MID (old) – 2004/22/EC – and new
- NAWI old – directive 2009/23/EC – and new
- EN 45501 (1992)
- OIML R76 Non-automatic weighing instruments (2006)
- Blue Guide of the European Commission (2000), currently under revision
WELMEC Guides concerning Software

• WELMEC guide 2.3 – Guide for Examining Software (NAWIDs), 2005
  – Describes essential properties of the software
  – Offers an effective, but not an extensive protection against manipulation
  – Harmonises software examination and documentation by the Notified Bodies as part of the type approval and testing procedures for NAWIs and related modules or peripheral devices.

• WELMEC guide 7.2 – Software Guide (MID), 2012
  – Describes a detailed system of requirements to and check of software of a measuring instrument.
  – Takes into account respective auxiliary devices as well
  – Currently under revision
  – Open points – e.g. “cloud” as long-term storage

www.welmec.org
Conclusions for PTB as a notified body

• Every part of a weighing instrument containing software needs:
  – A description
  – An identification
  – Security algorithms

• Following WELMEC 7.2
  – Examination level
  – Software protection
  – Conformity with directive

• But – on an adequate level
EMC – What for?

Electromagnetic interactions between environment and equipment

Protection requirements: Directive 2004/108/EC to electromagnetic compatibility
8.1 Design and construction of the instruments shall be such that the instruments will preserve their metrological qualities when properly used and installed and when used in the environment for which they are intended. [..]

8.2 When exposed to disturbances, electronic instruments shall not display the effects of significant faults, or shall automatically detect and indicate them.

Upon automatic detection of a significant fault, electronic instruments shall provide a visual or audible alarm [...].

8.5 The instruments shall have no characteristics likely to facilitate fraudulent use, whereas possibilities for unintentional misuse shall be minimal. [...].
Application in the field

Typical application for a NAWI:
10 V/m are reached in a distance of
- 0.6 m for 2 W – GSM mobile phones
- 1.1 m for a 8 W – GSM mobile phones
according to ISO 61000-4-3
Consequences

- Revision of OIML R76 in 2006 –
  - B.3.5 Immunity to radiated electromagnetic fields:
    - Frequency range: 80 MHz – 2000 MHz (28 MHz – 80 MHz see B.3.6)
    - Field strength: 10 V/m
- Thus, OIML R76:2006
  - Is the recent international harmonised technical recommendation
  - Established with participation of CECIP, NMIs, verification and market surveillance Authorities
  - Reflecting the generally acknowledged state of the art for non automatic weighing instruments
- Recommendation of WELMEC WG 2 to the Commission to revise EN 45501 and adopt OIML R76 (2006) in the standard.
Revision of EN 45501

- 05/2007 – mandate M/412 of the European commission
- 06/2011 – The Commission announced to publish a note
- 08/2011 – The JWG NAWI send a first draft to the CEN/CENELEC Management Center (CCMC)
- 09/2011 – Consequences of the announced note and the transition period are discussed in WELMEC WG2. The NBs agree with 10 V/m.
- 10/2011 – Decision for a fast track procedure for the current version of the revision under special conditions.
- 04/2012 – Vote on the current draft of EN45501:2011
  – Voting result: NO, because there were too much abstentions !!!
- 06/2012 – meeting of the JWG
- 11/2012 – a draft was sent to the Commission without incorporation of the aspects discussed with the JWG
- 03/2013 – new draft of the chair addressed to the national standardisation organisations for confirmation
- ...

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References:


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