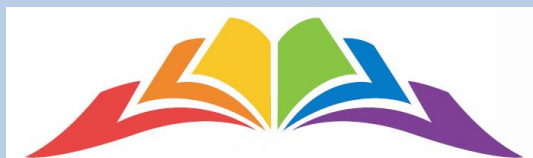


**Twinning Project “Strengthening the capacities of the Bureau of  
Metrology for internal market integration”  
Twinning ref. MK 12 IPA EC 01 16 TWL**



**A Project funded by the European Union and Implemented and led by CMI**

**EU MEASURING INSTRUMENTS  
DIRECTIVE (MID)  
GENERAL PRINCIPLES AND  
REQUIREMENTS**



**Pavel Klenovský, Czech Metrology Institute**



This Project is funded by the European Union



Project Implemented by the CMI





# European Union



- ❑ established by the Treaty of Rome in 1957, the treaty is that of Lisbon creating the EU
- ❑ nowadays a high level of **integration**: **common (single) market**, common currency – the EUR
- ❑ based on 4 **freedoms**: free movement of **goods**, services, persons and capital
- ❑ the **goal**: **elimination of barriers** caused by different regulations in the Member States (MS)





# European Union



- ❑ **EU** – a **zone of free trade** (and at the same time, a **customs union**)
- ❑ **consequently, the legislation has to be split into 2 parts:**
  - ❑ **harmonized regulated area** – e.g. **old-approach and new approach directives**
  - ❑ **non-harmonized regulated area** – **legislation on the national level + principles of mutual recognition**





# Secondary legislation



**Legal acts adopted by common legislative bodies (the Council, the EP):**

- ❑ **regulations** – immediately effective without any transposition on the national level (e.g. CAP)
- ❑ **directives** – have to be transposed into national legislations of MS, mainly used to built up the Single Market incl. technical requirements for products
- ❑ **decisions** – applicable only to those for which it is written (e.g. supervision over the competition)





# Secondary legislation



## Legal acts adopted by common legislative bodies (the Council, the EP):

- ❑ **recommendations, opinions** – not legally binding
- ❑ **resolutions** – gives attitudes and approaches of the EU to various problems
- ❑ **judgements of the European Court of Justice** – represents jurisprudence of the Court
- ❑ **Green and White Papers** – discussion documents (White Papers: strategic planning documents)





# Development of the secondary law



- ❑ **we are interested only in the elimination of technical barriers to trade with products (incl. MIs)**
- ❑ **since the sixties of 20th century so called **traditional (old) approach** was applied: all the details were described in the directives**
- ❑ **in the eighties this approach proved to be ineffective and it was a barrier to technical progress**





# Development of the secondary law



- on the other hand, the advantage was that **no important technical requirement was omitted** (various specifics of products could be taken on board) – see the unbearable situation in the area of medical devices (MDD)





# Development of the secondary law



- **in the nineties so called **new and global approach** for preparation of directives for technical requirements to products was introduced**
- **the primary goal here is **to strengthen the integration** (free movement of goods), **not primarily protection of public interests** (consumers) which is the main remit of legal metrology – a potential problem**







# New approach - principles



- ❑ **the harmonization is confined only to so called **essential requirements****
- ❑ **only products fulfilling the essential requirements are allowed to **be put on the market and into use****
- ❑ **harmonized standards** published in the **Official Journal of the EU** form a **presumption of conformity** with the **corresponding essential requirements**





# New approach - principles



- ❑ **the use of harmonized standards or other technical specifications is voluntary - manufacturers can freely choose any technical solutions establishing conformity with the essential requirements**
- ❑ **manufacturers can freely choose any combination of modules of conformity assessment given in the corresponding directive (to be carried out by either the manufacturer or so called Notified Body)**





# New approach - principles



- ❑ if a given product fulfills the requirements of **all the directives** that are related to it the manufacturer is permitted to draw up a **EU Declaration of conformity** and to affix the **CE marking (+ supplementary metrology marking in metrology)** to the product
- ❑ **CE marking (at least 5 mm high):**

**CE M 07 1383**



# New approach - principles



- ❑ unlike in the traditional approaches (everything had to be tested on the national level by an authorized body) **the new approach is built on 3 pillars:**
  - ❑ activities of **the manufacturer** + its legal liability for any damage caused by its product
  - ❑ the existence of totally independent **notified bodies** for given operations of conformity assessment
  - ❑ **market surveillance**

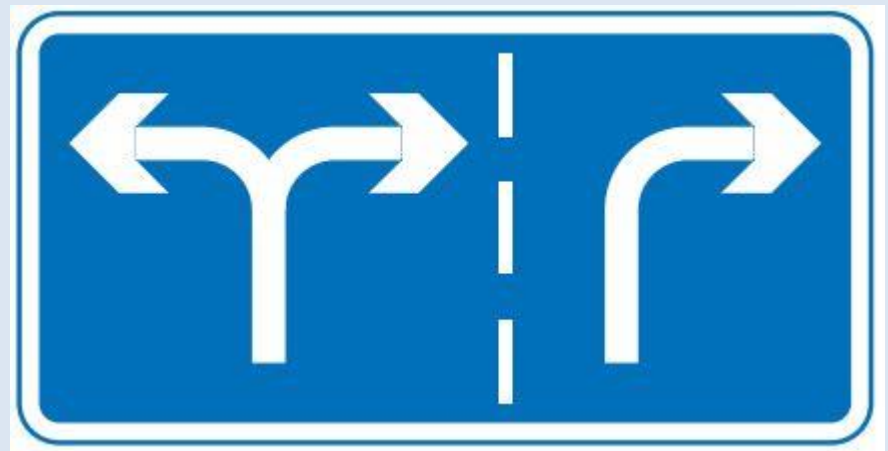
**NBs are not responsible for everything !**



# MID - history



- ❑ **the second new approach EU directive in metrology after NAWID**
- ❑ **the first version: 2004/22/EC becoming effective on October 30, 2006**
- ❑ **following the EU New Legal Framework revised as 2014/32/EU becoming effective on April 20, 2016**





# Scope



- watermeters**
- gasmeters + gas conversion devices**
- active electrical energy meters**
- heatmeters (**now** thermal energy meters)**
- measuring systems for continous and dynamic measurement of quantities of liquids other than water**
- automatic weighing instruments**
- taximeters**
- material measures**
- dimensional measuring instruments**
- exhaust gas analyzers**

# Which MIs are not covered

- capacity measures**
- level gauges**
- CNG dispensers**
- road tankers with level gauges**
- measuring systems for ethanol (used in small distilleries)**
- speedometers**
- breath analyzers**
- reactive electricity meters**
- measuring transformers**



# Basic structure



- ❑ **General provisions**
- ❑ **Annex I Essential requirements**
- ❑ **Annex II Modules of conformity assessment**
- ❑ **Annex III Instrument specific requirements (MI-001 Watermeters etc., MI-005 MIs for liquids other than water)**

**Note: the requirements of Annex I are often not taken into account(disregarded) !**





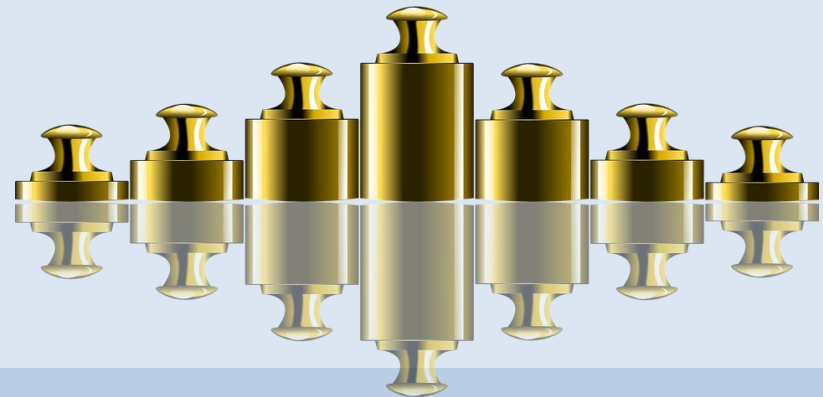


- ❑ **Art.7, par. 3** - a Member State may require a measuring instrument to satisfy provisions governing its putting into use that are **justified by local climatic conditions**
  
- ❑ in such a case, the Member State shall choose appropriate upper and lower temperature limits from Table 1 of Annex I and may specify humidity conditions (condensing or non-condensing)





- **Art. 8, par. 6** – when different **accuracy classes** are defined in the corresponding directive, then:
  - either their application is given by the product-specific requirements, or
  - a MS may determine the accuracy classes to be used for specific applications within the classes defined





## **Economic operators** – various duties are given by MID to them:

- manufacturer**
- authorized representative** - any natural or legal person **established within the Union** who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks
- importer** - any natural or legal person established within the Union who **places a measuring instrument from a third country on the Union market**



## Economic operators – various duties are given by MID to them:

- **distributor** - any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a measuring instrument available on the market





# General provisions – selected topics



- **Art. 7, par. 4** – manufacturers shall indicate on the measuring instrument their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, in a document accompanying the measuring instrument and on the packaging, if any, in accordance with point 9.2 of Annex I





- **Art. 22, par. 1** – the CE marking and the supplementary metrology marking shall be **affixed visibly, legibly and indelibly to the measuring instrument or to its data plate**
- where that is not possible or not warranted on account of the nature of the measuring instrument, they shall be affixed to the accompanying documents and to the packaging, if any

**CE** **M 07** **1383**



# General provisions – selected topics



- ❑ **Art. 46, par. 1 – the Commission shall be assisted by the Committee on Measuring Instruments**
- ❑ **that committee shall be a committee within the meaning of Regulation (EU) No 182/2011**
- ❑ **this Committee approves WELMEC guides to become official guidance to the implementation of MID**





## 1. Allowable errors (maximum permissible errors - MPE) – given in the instrument-specific annexes

- climatic, mechanical, electromagnetic environments, ambient humidity
- for MI-001 – 005 annexes the rule for **non-exploitation of errors** (originally in 2009/137/EC)



ERROR &  
MAXIMUM  
PERMISSIBLE ERROR





## 7. Suitability

- 7.1 A measuring instrument shall have no feature likely to facilitate fraudulent use, whereas possibilities for unintentional misuse shall be minimal.**
  
- 7.6. A measuring instrument shall be designed so as to allow the control of the measuring tasks after the instrument has been placed on the market and put into use. If necessary, special equipment or software for this control shall be part of the instrument. The test procedure shall be described in the operation manual.**



## 7. Suitability

- ❑ When a measuring instrument has associated software which provides other functions besides the measuring function, **the software that is critical for the metrological characteristics shall be identifiable and shall not be inadmissibly influenced by the associated software.**





## 8. Protection against corruption

- 8.1 The metrological characteristics of a measuring instrument shall not be influenced in any inadmissible way by the connection to it of another device, by any feature of the connected device itself or by any remote device that communicates with the measuring instrument.**
  
- 8.2. A hardware component that is critical for metrological characteristics shall be designed so that it can be secured. Security measures foreseen shall provide for evidence of an intervention.**





## 8. Protection against corruption

- 8.3. Software that is critical for metrological characteristics shall be identified as such and shall be secured.**
- Software identification shall be easily provided by the measuring instrument.**
- Evidence of an intervention shall be available for a reasonable period of time.**





## 8. Protection against corruption

- ❑ **8.4. Measurement data, software that is critical for measurement characteristics and metrologically important parameters stored or transmitted shall be adequately protected against accidental or intentional corruption.**





# CA modules – selected topics



- ❑ **2 aspects have to be covered:**
  - ❑ **conformity with essential requirements (typical module: B)**
  - ❑ **conformity with the approved type (typical modules: F or D)**
  - ❑ **both aspects can be covered by 1 module – e.g. module G**





- **Module B EU type examination**
  - **is the part of a conformity assessment procedure in which a notified body examines the technical design of an instrument and verifies and attests that the technical design of the instrument meets the requirements of this Directive that apply to it**
  - **based on testing of samples delivered by the manufacturer**

**SAMPLE**



- **Module B EU type examination**
  - is the part of a conformity assessment procedure in which a **notified body examines the technical design of an instrument** and verifies and attests that the technical design of the instrument meets the requirements of this Directive that apply to it
  - based on testing of samples **delivered by the manufacturer**
  - covers **conformity with essential requirements** only, similar to classical type approval





- ❑ **Module D Conformity to type based on quality assurance of the production process**
- ❑ **is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the measuring instruments concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them**





- ❑ **Module D Conformity to type based on quality assurance of the production proces**
- ❑ **the manufacturer shall operate an approved quality system for production, final product inspection and testing of the measuring instruments concerned and shall be subject to surveillance by a Notified Body of its choice (usually 1 in a year)**
- ❑ **covers conformity to the approved type only**





- ❑ **Module F Conformity to type based on product verification (EU verification)**
- ❑ **a notified body chosen by the manufacturer shall carry out the appropriate examinations and tests, or have them carried out, to verify the conformity of the instruments with the type as described in the EU-type examination certificate and the appropriate requirements of this Directive**
- ❑ **enables the use of statistical procedures (e.g. for communal MIs)**
- ❑ **covers conformity to the approved type only, similar to classical verification**



- Module G Conformity based on unit verification**
- a notified body chosen by the manufacturer shall carry out the appropriate examinations and tests set out in the relevant harmonized standards and/or normative documents to verify the conformity of the instruments with the applicable requirements of this Directive, or have them carried out and the appropriate requirements of this Directive**





- ❑ **Module G Conformity based on unit verification**
- ❑ **typical situation: the MI assembled on site from various parts and sub-assemblies as a unique MI**
- ❑ **the existence of an EU type examination certificate is not required !**
- ❑ **covers both conformity to the essential requirements and to the approved type**
- ❑ **rather typical for MIs for liquids other than water (MI-005), the WELMEC modular system is essential here**



# Main general features



- ❑ **optionality principle:** does not force any Member State to start regulating a MI under MID (if before they have been not regulated)
- ❑ **CA modules:** module A + modules with the accredited lab of the manufacturer (modules C) very rarely used
- ❑ **typical combinations:** B + D, B + F, G
- ❑ **a controversial module H** not applied, only its clone H1 (requiring **Design examination**), **CA according to module H not recognized outside Europe**



# Main general features



- ❑ **Annexes MI-001, MI-002, MI-003, MI-004 - MID includes only measuring instruments intended for residential, commercial and light industrial use (?) – no definition given up to now**
- ❑ **MI-001 (watermeters): old mechanical ones negatively influenced by intermittent flow, now prevailing**
- ❑ **MI-004 (heatmeters): „official“ sub-assemblies (flow sensor, temperature sensor pair and calculator), the complete instrument to be tested for integrity**



# Main general features



- ❑ **MI-008, chapter II Capacity serving measures: module A1 deleted, replaced by module A2**
- ❑ **modular approach** (voluntary system of modular evaluation - WELMEC doc. 8.8)  
– a concept outside the harmonized legislation, important for module G frequently used for MIs MI-005, **evaluation certificates for parts and sub-assemblies**





# Main general features



- ❑ **What if technical requirements are changed (e.g. by way of a harmonized standard) ? Do the issued certificates remain valid ?**
- ❑ **Yes, but both manufacturers and NBs have to start working on adapting the products to the new requirements.**
- ❑ **NBs: need to operate EMC testing facilities and SW validation unit**



# New influences/challenges



- ❑ hardware parts being replaced by **software** more prone to manipulations (validation/testing of SW)
- ❑ **download of new SW**
- ❑ **mobile communications** – remote fraudulent control of MIs by mobile devices
- ❑ everything should now be **smart**
- ❑ **shared economy** (Uber – taximeters)
- ❑ **GPS systems**



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