CZECH METROLOGY INSTITUTE

PRINCIPLES OF ASSURANCE OF METROLOGICAL CONTROL

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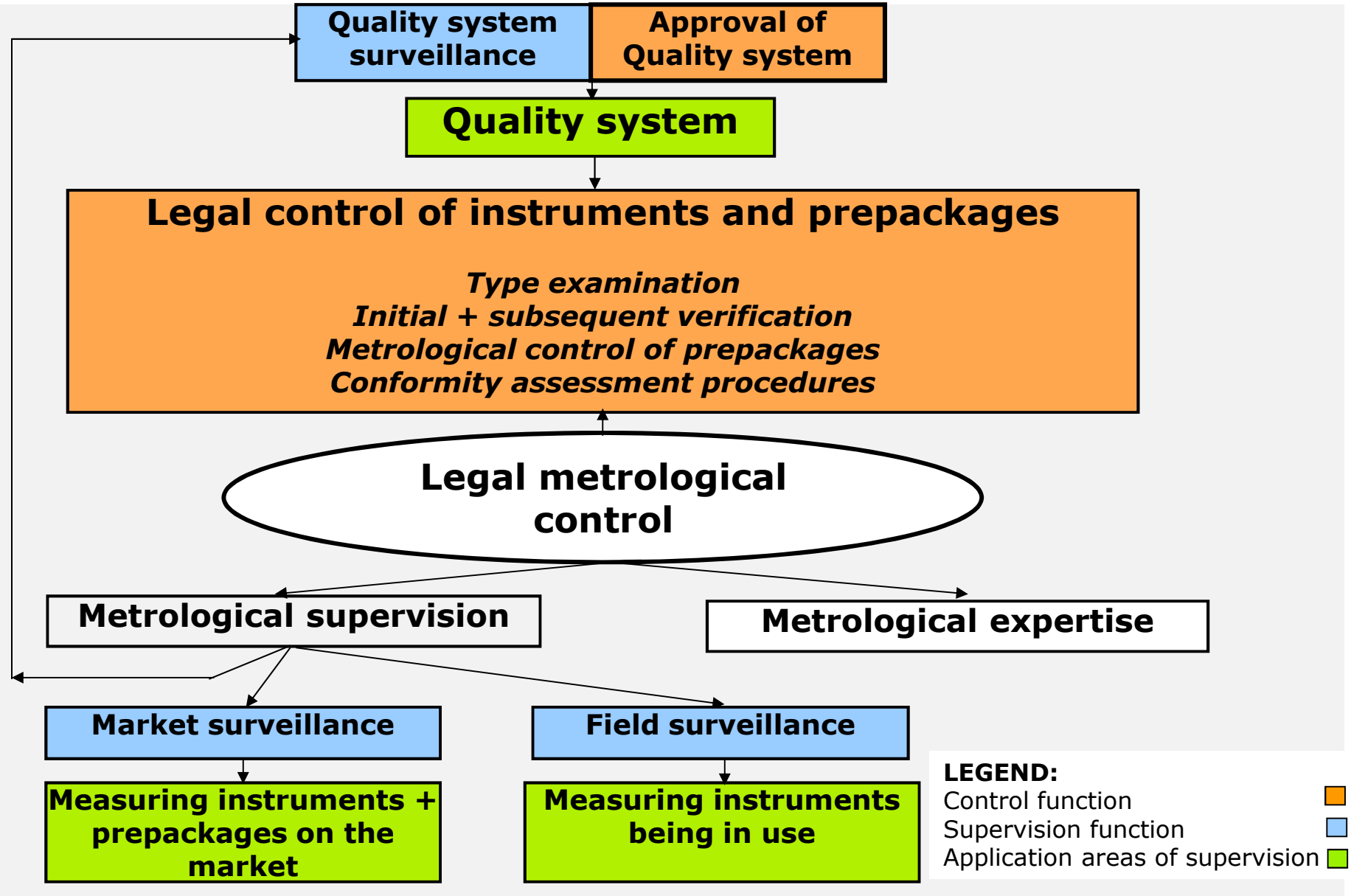
Legal metrological control

The fundamental goal of legal metrology (LM) - to provide effective protection of public interests associated with measurements

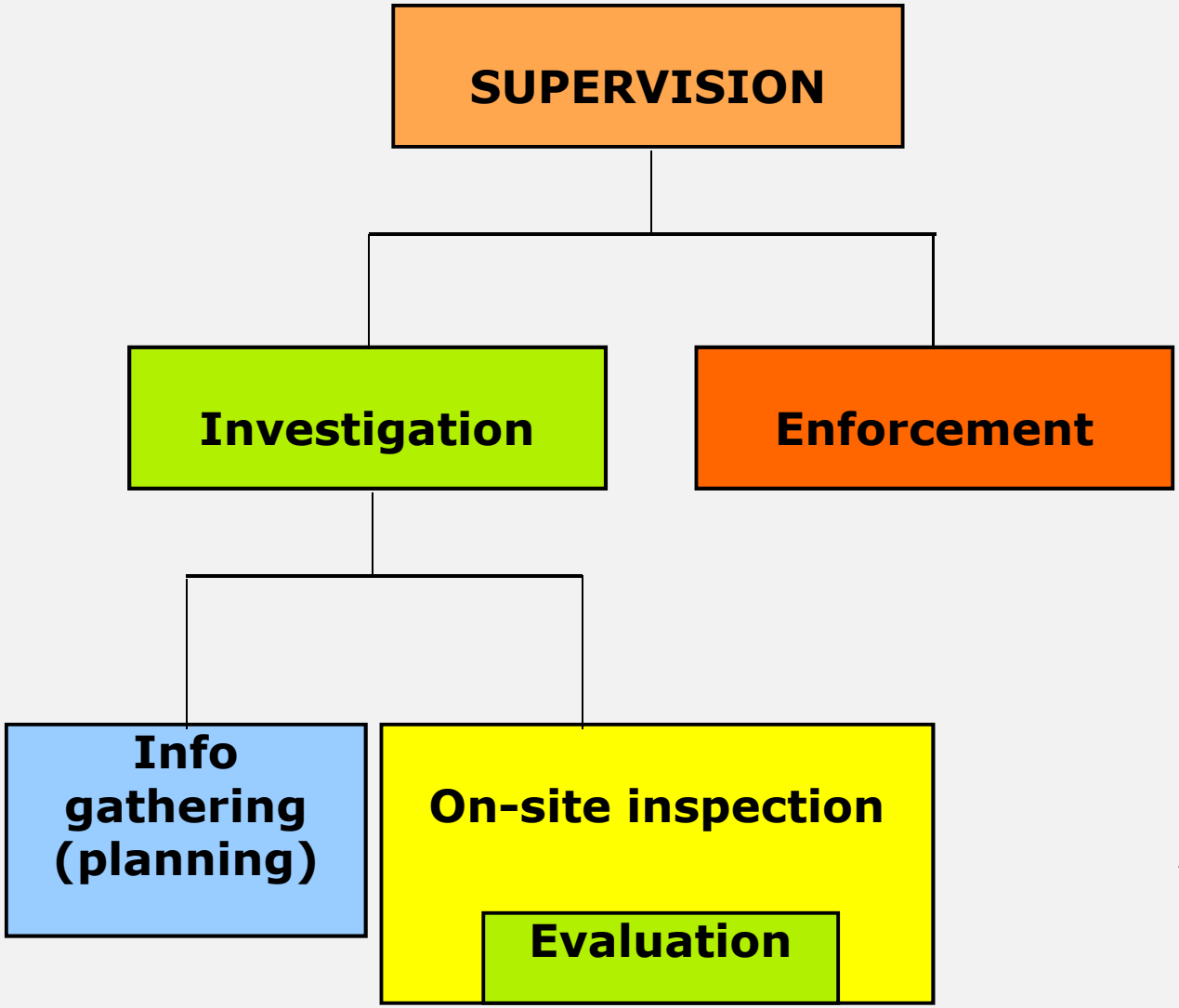
Legal metrological control, according to its definition, includes three main elements:

- **legal control of measuring instruments and of prepackages**
- **metrological supervision**
- **metrological expertise**

Structure of metrological supervision



Structure of metrological supervision



Structure of metrological supervision

Planning → **Inspection** - - - → **Enforcement**

Legal metrological control

The existing infrastructures of metrological control and their expertise can be used with advantage for those forms of control specified by other legislation:

- **prepackages**
- **gaming machines**
- **tachographs**
- **whole measurement process**

when measurements are made to demonstrate compliance with statutory requirements (such as the measurement of the level of noise in public places, measurement of pollution, etc.)

Legal metrological control

OIML D 16:2011
Principles of Assurance of Metrological Control

OIML D 9:2004
Principles of Metrological Supervision

OIML D 1:2012
Considerations for a Law on Metrology

OIML V 1:2013
International vocabulary of terms in legal metrology (VIML) – terminology to be used

- **represent a core basis of legal metrology anywhere**
- **they are mutually intertwined**
- **first 2 prepared by OIML TC3/SC2, secretariat: the Czech Republic**

Basic facts and approaches

- Both documents should reflect the true current (lie) situation worldwide
- Globalization – formation of free trade areas (EU) to eliminate technical barriers to trade – legislation split into 2 parts: putting instruments on the market and into use versus instruments in use
- Conflicting interests influence LM very much – technical competence is not enough, impartiality plays a crucial role
- The matters of LM are prone to intensive lobbying, especially on the part of the economic operators involved – on the other hand, consumers are never directly involved in this process

Basic facts and approaches

- With rising energy, water etc. prices, citizens are now very attentive to what regulated instruments measure – checks (tests) on instruments on site (within their period of verification)

- The arrangements in LM are, due to a long history of being cultivated by various national authorities, vastly fragmented across the world (and, by the way, across Europe as well)

Basic principles

1. The system of assurance of metrological control depends on what one tries to achieve

2. The total measurement process should be considered before developing or changing a metrological control system (includes the instrument, operator, environment, procedure and special characteristics of the item being measured)

3. To apply a feedback control to the process of making controlled measurements - identifying and subsequently implementing opportunities for improvements (an open-loop system" approach, i.e. without any feedback, is employed in most traditional metrology control systems

Basic principles

4. **Flexibility** in legal requirements allows officials to be selective in the application of controls (control history) – also allows legal authorities to distribute the burden of compliance to both users and manufacturers (by allocating them various roles and obligations in the whole process – European system of conformity assessment)

5. The system has to be kept **in line**, with a necessary inertia, providing stability, **with current technological progress and with prevailing trends in an overall economic background**, both locally and globally

6. **Proportionality:** actions taken to ensure confidence in the reliability of measurement should be costted, and the costs considered with respect to the benefits

Basic elements of the system

1. **The scope of LM control has to be defined – see above, countries normally adopt and publish a list of measuring instruments subjected to metrological control and/or a harmonized legislation is in place in a free trade area**

2. **Technical regulations for individual kinds of measuring instruments and of prepackages covering both their pre-market and post-market operational life, if applicable (ideally, these regulations should also contain instructions, wherever applicable, for installation and use of those instruments), structure similar to new approach of the EU**

3. **Harmonization of the technical regulations should be accomplished to the greatest extent possible - at least on a regional level, if not globally - to eliminate technical barriers to trade**

Basic elements of the system - EXAMPLE

BREATH ANALYSERS:

- CMI is at present the only body in the CR authorized to verification of breath analysers used by Police to enforcement
- There is an eternal dispute between „breath fans" and „blood fans": since the inclusion of breath analysers among regulated MIs and their use by Police we have been under attack from forensic doctors and we have had to fight back
- It is a clash of 3 different qualification communities: of metrologist (breath analysers as MIs), of chemists (methods of analysis of alcohol in blood) and of forensic doctors (the influence of alcohol on human body) – to find a common ground is extremely difficult
- More than anywhere else the well-known Churchill´s quote is applicable here: „I do not trust any statistics that I myself have not manipulated"

Basic elements of the system - EXAMPLE

BREATH ANALYSERS:

- **Main battleground: is the conversion factor between the contents of alcohol in breath and in blood sufficiently independent of individual human properties?**
- **Studies indicate that the uncertainty of this factor might be 25 %**
- **Studies show that this factor has a comparatively large uncertainty – but the coefficient used by forensic doctors to conversion of the contents of alcohol in blood to the time when the measurement by a breath analyser was made is in the following limits (de facto, the speed f alcohol degradation in a human body):**

$$0{,}12 - 0{,}20\ g.kg^{-1}.h^{-1}$$

- **If we are not concerned by an individual but by the whole population we can write it as $\beta_{60} = 0{,}16 \pm 25\ \%$, where the uncertainty is on the level with the above conversion factor!**

Basic elements of the system - EXAMPLE

BREATH ANALYSERS:

- It is interesting that, given the importance of the matter, there is no European-wide legislation on breath analysers nor it is subject to any kind of research on the part European research institutes, e.g. EU JRC IRMM

Basic elements of the system

4. **Involvement of authorized (licensed) private bodies** in some activities of metrological control, especially in subsequent verification – it can touch pattern approval and initial verification, most common case is when **instrument repair firms with a demonstrated competence are authorized to perform verifications following instrument repair**

5. **Split legislation** into two parts in free trade areas covering measuring instruments being put on the market (the market stage) and measuring instruments in use (the in-service stage) – more extensive involvement of manufacturers, this system is called **conformity assessment**

6. **Proper selection (combination) of control elements** to individual measurements (measuring instruments

Basic elements of the system

7. **Adopting a total systems approach can the elements of the process be put into proper perspective and the total process performance adequately assessed – measurements can retain sufficient accuracy on a continuing basis to meet requirements, even though certain control elements may have been relaxed or eliminated, e.g. through the optimization of reverification periods**

Essential technical elements of MC

a) A set of maximum permissible errors (MPEs) is defined for each controlled measurement category of instruments - each set includes MPEs for verification and MPEs for in-service surveillance (usually extended MPEs for verification)

b) The total uncertainties of the tests (measurements) made by verification officers are continually monitored and kept sufficiently small as required by regulations so that accept/reject decisions are reasonably little influenced by these uncertainties (but still a grey zone exists) - the regulations must specify how to take these uncertainties into account when making decisions on compliance (the principle of shared risk is often applied here) x ISO 17025, JCGM 106:2012

c) Tests are carried out under actual or simulated conditions of use

Essential technical elements of MC

d) **A reasonable amount of data is routinely gathered** so that causes of non-compliance can be identified by data analysis – unfortunately, **obstructed by the activities of servicing organizations**

e) **Institutional factors (social, legal, and economic) are arranged,** if possible, so that rapid, appropriate action can be taken by legal metrology officials, manufacturers, instrument services, etc., to reallocate surveillance efforts by metrology officials or to correct conditions producing non-conformance

Framework of the system

Typical combinations of control elements to be used in application to the various existing situations in the present-day legal metrology are as follows:

- **measuring instruments at the market stage;**
- **measuring instruments in service;**
- **metrological control of prepackages;**
- **complementary activities of metrological control**

- **Financing of the activities: the authorities have to find the optimum between the total cost for society of the system chosen and the accepted level of confidence in the measurements, regardless of who is doing what and which activities are needed**
- **Mainly a national matter, tricky in this world**

MIs at the market stage

Pre-market approach

1. **A highly restrictive legal metrology control system typically includes, by law and regulation, all of the following:**

   - **type evaluation and type approval of measuring instruments;**
   - **installation requirements are laid down;**
   - **initial verification both at the factory and at point of use;**
   - **environmental requirements (EMC etc.)**

➲ **all the operations are performed by legal metrology officials, normally for a fee**

MIs at the market stage

2. A balanced system can be based on:

- **Type evaluation and type approval carried out by competent bodies (accredited or peer reviewed - generally called conformity assessment bodies) with a maximum mutual recognition of either type approval certificates or corresponding test reports (e.g. OIML MAA, EU global approach);**

- **Initial verification by the manufacturer (in the factory) based on an assessment of his quality management system by a competent body (an accredited certification body for quality management systems having expertise in the given field), the existence of an over-arching certified quality management system (QMS, based on the ISO 9001:2008) is taken into account - QMS assessed in this way is subsequently subject to regular quality surveillance as one form of metrological supervision (see OIML D 9)**

MIs at the market stage

2. A balanced system can be based on:

- **Type approvals are not required when they are impractical and they do not add much to the protection of the public interest (e.g. capacity serving measures) - in those cases, only initial verification is carried out**

- **As to initial verification, this system is applicable to a majority of measuring instruments with the exception of those which, for various reasons, have to be verified in-situ (e.g. instruments of which the measuring performance can be typically dependent on the location of use, for instance the height above sea level, e.g. non-automatic weighing instruments of class I, II, sometimes III and exhaust gas analyzers)**

MIs at the market stage

3. A highly liberal system can be developed from the balanced system by (something like module H in Europe):

- **Extending the assessed QMS to cover the design stage of those measuring instruments (the R&D operations of the manufacturer)**
- **The relevant competent body, having assessed this more complex QMS, would subsequently assess technical documentation of any new type (design) of the measuring instrument (resulting eventually in the issuance of a design certificate)**

- **In this system, no third-party testing is required - it can be assumed that the majority of tests will be carried out by the actual manufacturer**
- **Instead, there is third-party assessment of the technical documentation**
- **Obviously, it is prone to frauds and does not present very good protection of public interests (see breast implantats)**

MIs at the market stage

Post-market approach

- To reduce the activities of metrological control at the market stage to their bare essentials (possibly only initial verification)
- And at the same time to strengthen market surveillance
- Initial verification done by manufacturers at their sites (wherever possible) would be recognized until actions of market surveillance clearly demonstrate an unacceptable performance - in such a case, legislation could require initial verification to be done in-situ at the expense of the manufacturer

➲ This system might be demanding on litigation and financial resources, but theoretically quite flexible

MIs at the market stage

Post-market approach

- **Reasons behind: gold-plated instruments, the validity of initial verification done by manufacturers on their own sites can be compromised by long logistical routes (such as overseas transportation) or by exposure to external influence factors (e.g. electromagnetic interference, extreme ambient conditions)**
- **This point-of-use or end-point strategy offers a robust protection to the public**
- **Proposed by Australia (under buzzword: conformity to type) which does not manufacture any MIs and it totally dependent on their importation**

MIs in service - MODELS

1. **GERMAN MODEL** - **subsequent verification** (either **periodical** or **after a repair**) of legally controlled measuring instruments **charged to their users** complemented by actions of **in-service surveillance** (as a form of metrological supervision - see OIML D 9)

FEATURES:

- All the activities are normally carried out by a single government body (authority) in any given constituency
- **Fees are charged for verification**, this system of legal metrology has been designed to impose a **minimal burden on taxpayers** but the existence of **fees attracts the interest of the private sector**
- **Users cannot be held solely responsible for non-compliances** with the regulations after being subject to a mandatory operation in fixed intervals for which they have to pay

MIs in service - MODELS

1. **GERMAN MODEL** - **subsequent verification** of legally controlled measuring instruments **charged to their users** complemented by actions of **in-service surveillance** (as a form of metrological supervision - see OIML D 9)

FEATURES:

- Together with type approval and initial verification, the whole system by itself should guarantee a **continual compliance** of those measuring instruments with the regulations
- With a relatively high degree of impartiality (since tests are performed by a third party body but charged to those being controlled) this arrangement **is the best one if the government legal metrology services involved are flexible enough** in their operation to be able to manage the necessary coordination with servicing organizations when verification is performed in-situ

MIs in service - MODELS

1. GERMAN MODEL - subsequent verification of legally controlled measuring instruments charged to their users complemented by actions of in-service surveillance (as a form of metrological supervision - see OIML D 9)

FEATURES:

- The whole system was originally designed with the aim of really providing this guarantee but in the course of development the amount of testing had to be reduced due to various pressures - the integrity of the system, if additional counter-provisions have not been employed, has therefore been relaxed so that sometimes we can speak only about a minimization of the associated risk
- The operation of the system in real life is negatively influenced by real or artificial needs of repairs, repairers in most cases being closely associated with either manufacturers or users

MIs in service - MODELS

1. GERMAN MODEL - subsequent verification of legally controlled measuring instruments charged to their users complemented by actions of in-service surveillance (as a form of metrological supervision - see OIML D 9)

FEATURES:

- In many countries verification has been passed over to licensed (authorized) or accredited bodies either fully (France, Sweden) or only for measuring instruments outside W&M (Germany, Switzerland, Austria until 2004, Czech Republic, Slovakia)
- The area of classical W&M (weighing instruments, fuel dispensers, taximeters, material measures) can be distinguished here: these instruments are characterized by their subsequent verification being performed on site and by their use for direct charging of payments (for a delivery of quantity of goods) to consumers (citizens)

MIs in service - MODELS

1. **GERMAN MODEL** - **subsequent verification** of legally controlled measuring instruments **charged to their users** complemented by actions of **in-service surveillance** (as a form of metrological supervision - see OIML D 9)

FEATURES:

- The reasons why not to use authorized bodies in some situations of subsequent verification (mainly for verifications made on site) will be given later
- The pressure exerted by users to keep the fees as low as possible **does not usually enable a systematic gathering of data** in the process of verification itself

MIs in service - MODELS

2. **AMERICAN MODEL** - subsequent verification of legally controlled measuring instruments **not** charged to their users

FEATURES:

- The scope of regulation is **limited to W&M** and measuring instruments are verified (inspected) at fixed time intervals by (national or local) government authorities
- **No fee is charged to the users** in line with the argument that users of measuring instruments should not subsidize any protection of public interests in metrology
- The logical consequence is that **the user is solely responsible for keeping his/her instruments in compliance with the regulations**

MIs in service - MODELS

2. **AMERICAN MODEL** - subsequent verification of legally controlled measuring instruments **not** charged to their users

FEATURES:

- He term "subsequent verification" is used here to retain some sort of unified terminology – it is clearly **a combination of verification and supervision** (which is sometimes called **enforcement**, sometimes **inspection**, adding to the confusion – see VIML and OIML D 9)
- In the current circumstances the obvious liability in this system is its **sole dependence on funding from public sources** – these could be scarce and the operation of authorities could be severely hit by budget cuts
- Another disadvantage might be **the difficulty in motivating officers to be flexible enough** in their operation

MIs in service - MODELS

2. **AMERICAN MODEL - subsequent verification of legally controlled measuring instruments not charged to their users**

FEATURES:

- **On the other hand, the ability to make hard decisions impartially is ideal here**
- **The system presents no direct financial burden to users**
- **From the viewpoint of feedback, this model is quite suitable for systematic data gathering on the performance of the control system**

MIs in service - MODELS

3. **DUTCH MODEL – no (mandatory) subsequent verification of legally controlled measuring instruments, only metrological supervision over them**

FEATURES:

- **The government authority carries out supervision over measuring instruments specified by the regulations based on its own plan of inspections in the field, at the very least, this would apply to W&M instruments**
- **The authority could be a Government executive agency or a nominated private body**
- **There is no fixed period of time to make an inspection, it depends on the outcome of the results each year and is based on risk analysis - every measuring instrument is inspected once every four or five years**

MIs in service - MODELS

3. **DUTCH MODEL – no (mandatory) subsequent verification of legally controlled measuring instruments, only metrological supervision over them**

FEATURES:

- **No subsequent verifications in regular intervals are carried out by force of legislation - however, subsequent verification may be mandatory after repair or when a seal is broken**
- **Users are solely responsible for compliance of their instruments with the regulations in place and are free to take any measures that are necessary to achieve that**
- **Again, being financially dependent solely on public funding, the stability of this system is questionable under circumstances when public funds are under a severe squeeze**

MIs in service - MODELS

3. **DUTCH MODEL – no (mandatory) subsequent verification of legally controlled measuring instruments, only metrological supervision over them**

FEATURES:

- **the system is impartial and is of no direct burden to any stakeholders in this business, whether they be users, manufacturers or servicing organizations**
- **another advantage is the flexibility of the officers in their operation because the nominated independent private body is aware of the needs of all stakeholders (consumers, policy makers and users)**
- **this is an example of a model with minimum control interventions**
- **from the viewpoint of feedback, this model could be considered the second most effective one after the previous model**

MIs in service – ADDITIONAL COMMENTS

- **Subsequent verification should not be required when the metrological properties of some measuring instruments cannot technically change until they are broken (capacity serving measures, liquid-in-glass thermometers, etc.)**

- **Subsequent verification is always required after repair, and whatever the circumstances there are always some arguments that repairers should be authorized to perform it - on the other hand, if impartiality is considered more important, measures have to be taken to secure a fast and flexible service on the part of the legal metrology authority (in this case, instruments can immediately be put into service after repair by way of a special repairer's stamp valid for a fixed period of time – e.g. three weeks)**

MIs in service – ADDITIONAL COMMENTS

- When the possible involvement of private bodies in in-service metrological control is contemplated, attention has to be paid to the issue of whether an adjustment to the measuring instrument under test can only be part of a repair, or whether it can be part of subsequent verification as well

- The application of statistical methods to their verification (verification by sampling), and for an extension of the reverification periods of individual batches

- Necessity to analyze modern trends in frauds associated with measuring instruments and to design appropriate countermeasures: hard frauds – turbo (taximeters, fuel dispensers), soft frauds – manipulation with errors within MPEs

- Unannounced actions of metrological supervision consisting of purchasing goods in the field by inspectors pretending to be normal customers are remedy here

MIs in service – ADDITIONAL COMMENTS

- To tackle these "soft frauds", legislation has to be adapted, as is already the case in the EU by way of revision of MID by Directive 2009/137/EC for annexes MI-001 up to MI-005

- Problems with the EMC susceptibility of weighing (and other) instruments: the testing levels given by harmonized standards or documents are too low compared with levels readily available in the field

- In current OIML R 76-1 this limit has been increased to 10 V/m in line with OIML D11:2004 while current (analogue) walkie-talkies and digital cellular phones are able to generate up to 100 V/m, depending at short distance, a 2 W GSM telephone typically produces field strength of 10 V/m at a distance of 0.6 m

MIs in service – EXAMPLE

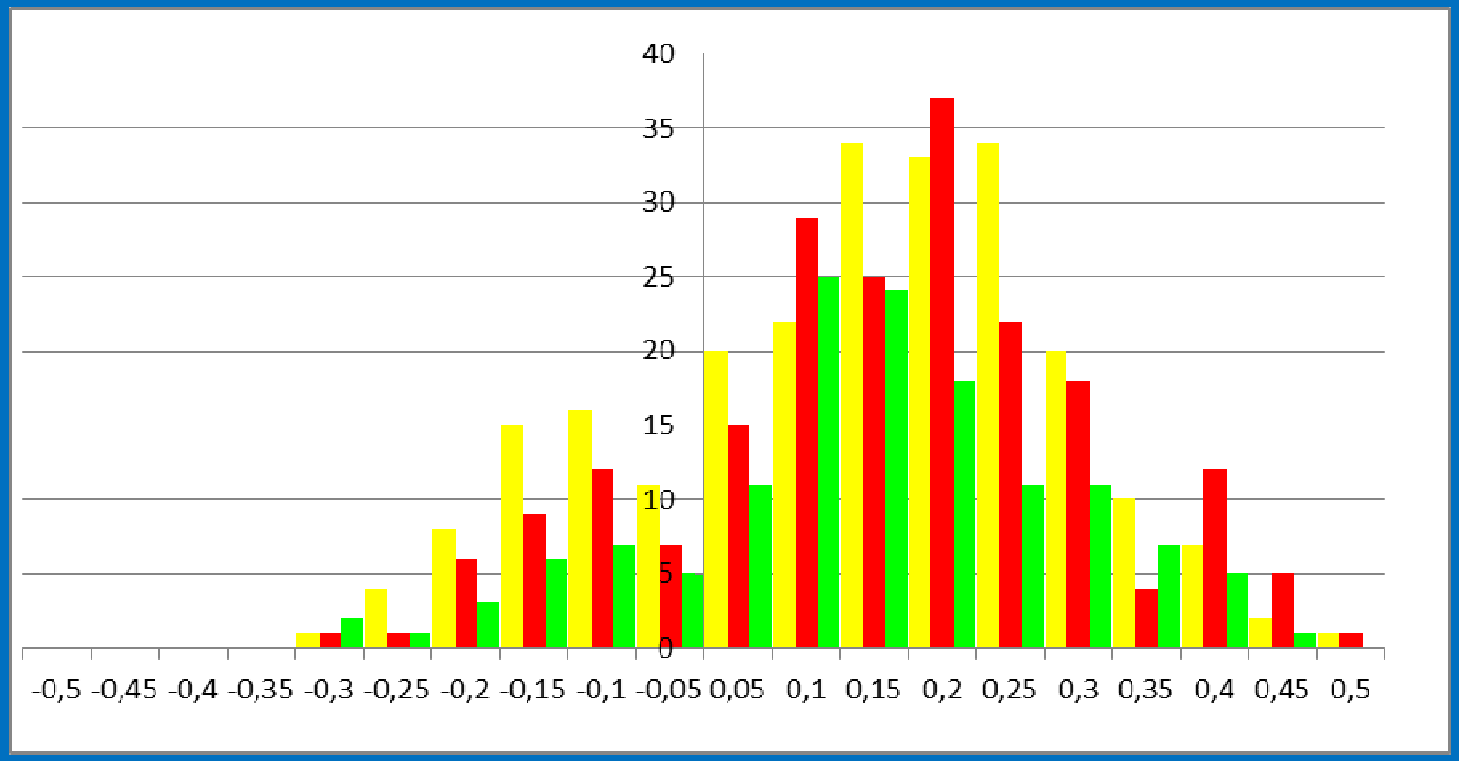
- **Fuel dispensers with MPEs of 0.5 % for normal fuels (not for liquefied gases): "soft fraud" consists in setting the error to a level very close to the tolerance limit, in favor of the user of the fuel dispenser**
- **This requires collusion between repairers and users on demand from the latter and this could happen any time, not just immediately before verification**
- **In the Czech Republic, an OECD member, this 0.5 % means 300 ppm of GDP of unjustified profit in favor of fuel distributors at the expense of consumers annually**
- **It is roughly ten times greater than the total amount of subsidies which those countries invest annually in their national metrology systems**
- **Using MPEs in-between subsequent verifications it is double the sum (they are 2x MPEs at verification)**

MIs in service – EXAMPLE

- At the same time, the total of verification fees is at 4.5 ppm of GDP annually – a negligible sum compared with the benefit from the manipulation
- Freedom from any commercial interests (in other words, a monopoly of an authority or a body linked to the local government) is the only way how to bring this kind of fraudulent behavior under control - the same type of argument is used to justify the national monopoly position of accreditation bodies
- A similar arrangement is used for Notified Bodies in the European conformity assessment system

MIs in service – EXAMPLE

Fuel dispensers in service 2011 – 2013 in the Czech Republic



Metrological control of prepackages

- **A prepackaged product is a single item for presentation as such to a consumer**
- **It consists of a product of predetermined quantity, and of the packing material into which it was put before being offered for sale**
- **The packing material may enclose the product completely or only partially, provided that the actual quantity of product cannot be altered without the packing material either being opened or undergoing a perceptible modification**
- **Packing goods for sale has moved from commodities sold in bulk to prepackaging**
- **Any reasonable system of metrological control has to be based on a control at the manufacturing stage**

Metrological control of prepackages

- **Legal metrological control is based here on an assessment of the QMS of the packer aimed specifically at compliance of the system with the requirements of the relevant regulations during packing + regular quality surveillance**
- **Any reasonable system of metrological control has to be based on a control at the manufacturing stage**
- **Various systems exist:**
  - **Maximum negative deviations**
  - **The „e" mark in the EU - voluntary system based on a special marking as a tool to eliminate technical barriers to trade with these products (not primarily as a tool of consumer protection), regulation based on the batch average requirement**
  - **OIML R 87**

Metrological control of prepackages

- **Various systems exist:**
  - **An ideal regulation here should cover all the prepackaged products without any limitations (no nominal quantities, limiting sizes, metrological quantity, nature of products)**
- **What to do with non „e"-marked products in an EU Member State?**
  In a project in our country 62 % of collected samples failed based on requirements given by the consumer protection legislation (not a single sample of a batch shall be under the declared mass or volume)

Complementary activities of MC

Metrological expertise:

- Any jurisdiction has to establish how to make measurements that could be used in court or to decide upon infringements on the rights of various bodies
- The total measurement process should be captured here, not only the measuring instrument itself
- Technical competence of those bodies making official measurements can be demonstrated by accreditation or by assessment on the part of metrology authorities
- Though this field is normally regulated separately by various government departments, it could usefully be included in metrological legislation

Complementary activities of MC

Arbitral tests (verification within the statutory period):

- metrological legislations should contain a provision for tests of MIs in case of disputes between distributors and consumers or complaints on the part of consumers
- it is an urgent matter in case of communal MIs like watermeters, heatmeters, electricity meters and gasmeters
- one solution is that, on request from a consumer, the distributor would arrange for such a test in an authorized metrology centre – when the instrument fails the test is paid by the distributor, when passes the consumer pays
- such a system has proved to be flawed
- an alternative approach: to make those measurements on site with the instrument under test installed
- a special instrumentation for this purpose has to be prepared
- it has a very high political potential in favour of legal metrology services

Complementary activities of MC - EXAMPLE

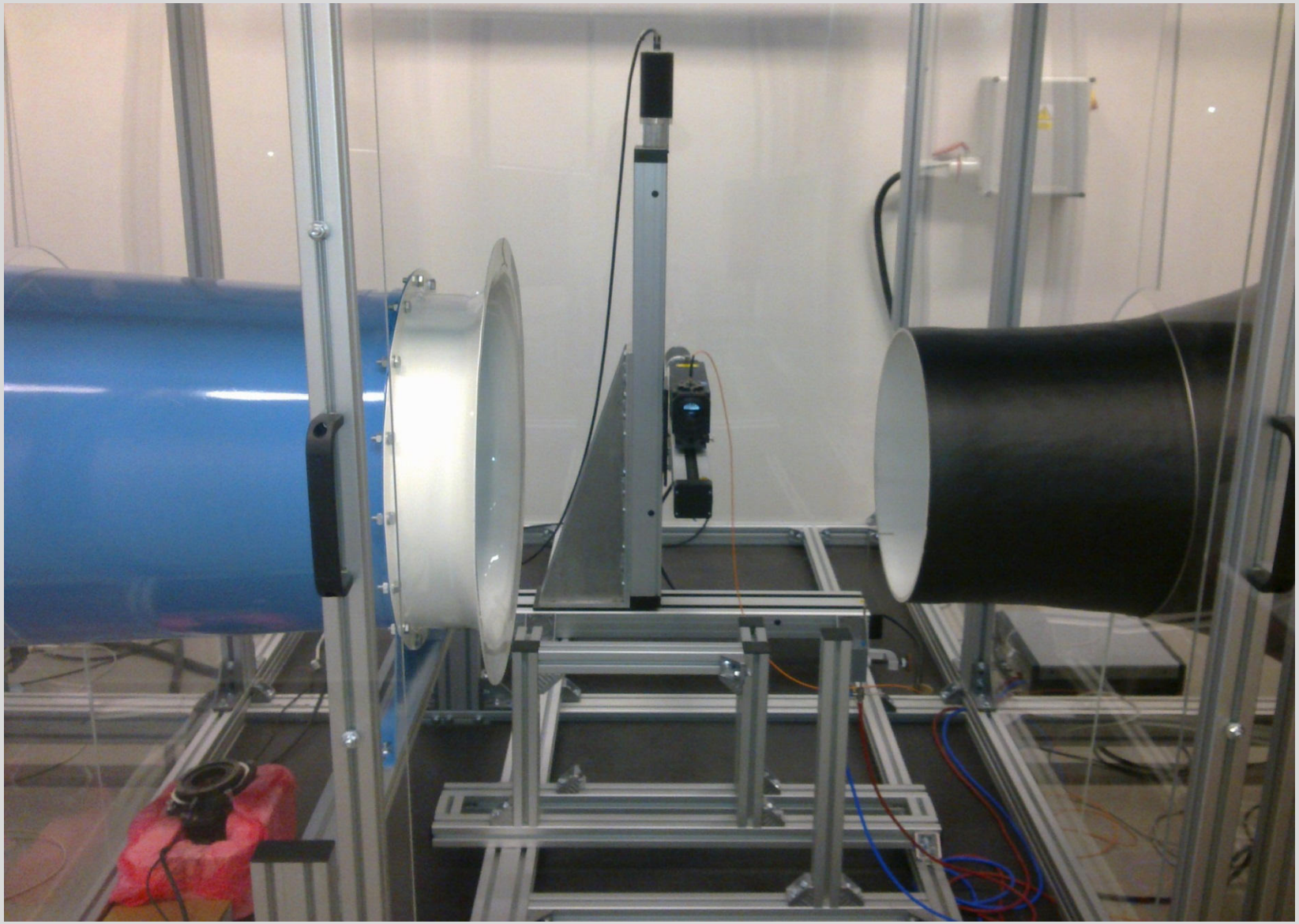
Recent developments

Recent developments

Recent developments

Recent developments

Recent developments



Recent developments

THANK YOU FOR YOUR ATTENTION!

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