



CIML Round Table on “Metrological Control”

Wednesday, 28 October 2009

9.00 to 12.30



In the past metrological control was a national task.

Today it is and in the future it will be a regional and world wide challenge.

OIML has to deal with these developments.



The following OIML Publications are currently under revision:

D 1 “Elements for a Law on Metrology”, TC 3/SC 5

D3 “Legal qualification of measuring instruments”, TC 3/SC 1

D 16 “ Principles of assurance of metrological control”, TC 3/SC 2

D 19 “Pattern evaluation and pattern approval”, TC 3/SC 1

D 20 “Initial and subsequent verification of measuring instruments and processes”, TC3 1

The themes which will be examined in the Round Table are the following:

1. Total systems approach to metrological control: should measurements be regulated rather than measuring instruments?
2. Metrological control in the future:
 - moving the center of gravity from pre-market to post market control,
 - may the different operations be carried out independently (for example type evaluation and production evaluation)?
3. Delegation of certain operations to private bodies versus keeping them in state or state-run bodies, discussion of current systems of in-service metrological control, possibilities of accepting first part conformity evaluations, test results and/or declarations of conformity (manufacturers, repairers, etc.).
4. How to maintain a satisfactory level of knowledge of and control over the actual overall quality of instruments in service?
5. Meaning of MPEs at different stages of the life of an instrument: design stage, production stage, before/after first installation, at inspection, in service, after repair; use of uncertainty evaluation in these cases.

Organization of the Round Table

Moderator

Manfred Kochsiek

Presentations (each 10 to 15 minutes)

Jean-François Magaña: ...

Stuart Carstens: ...

Pavel Klenovský: ...

Corinne Lagauterie: ...

Jean-François Magaña: ...

Discussions with all participants and Round Table presentors

Conclusion

Jean-François Magaña

Manfred Kochsiek



Conformity assessment a new approach

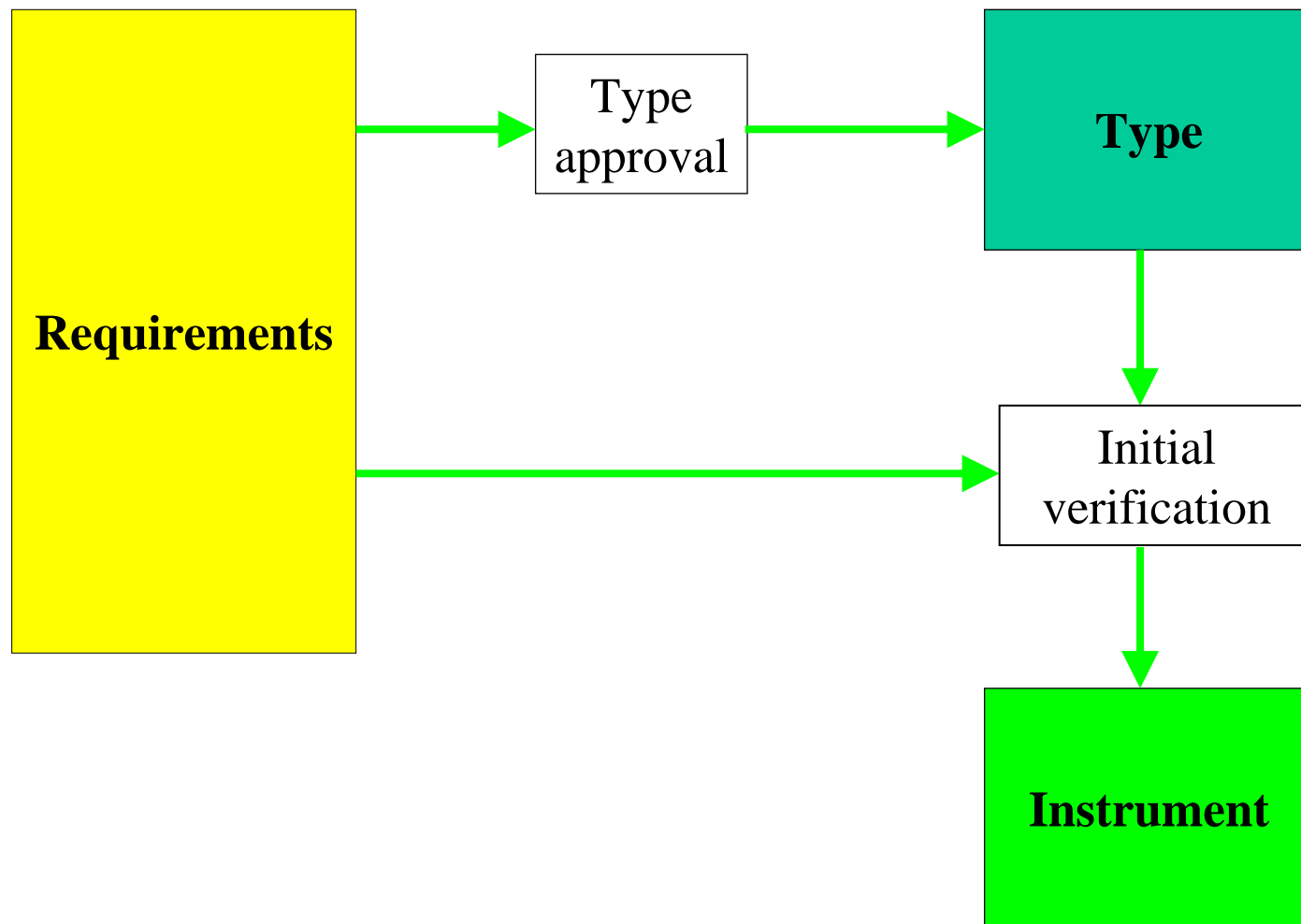
*J.F. Magaña
BIML Director*



Traditional Legal Metrology Control

Traditional Legal Metrology Control is composed of 2 complementary procedures:

- Type approval (or OIML Certificate),
- Initial verification, which includes an assessment of conformity to type



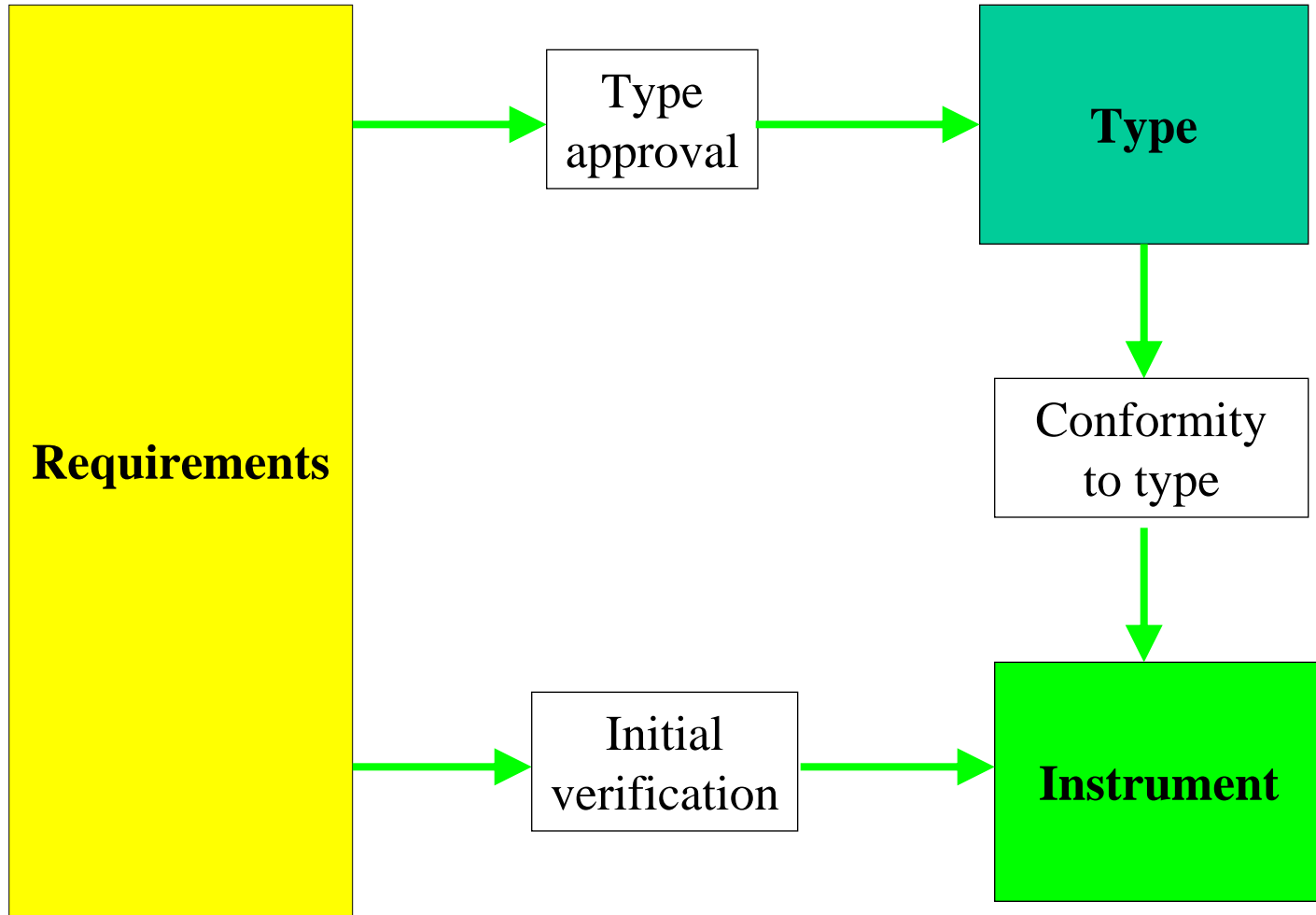


Proposed new scheme

Legal Metrology Control should be composed of 3 complementary procedures:

- Type approval (or OIML Certificate),
- Conformity assessment,
- Initial verification.

Proposed new scheme





Type of measuring instrument

Conformity to type requires to define clearly **what is a type.**

A type means

- something which represents the envisaged production,
- conformity with which has to be assured

A type should be a set of:

- design documentation,
- specifications of supplies,
- manufacturing processes,

that allow to conclude that conformity to type ensures compliance with the appropriate requirements.

Then initial verification may be restricted to a limited number of other features.



Type approval

A type approval requires to evaluate:

- whether the examined instruments are representative of the envisaged production,
- whether they comply with requirements whose compliance shall be inherited by instruments produced.

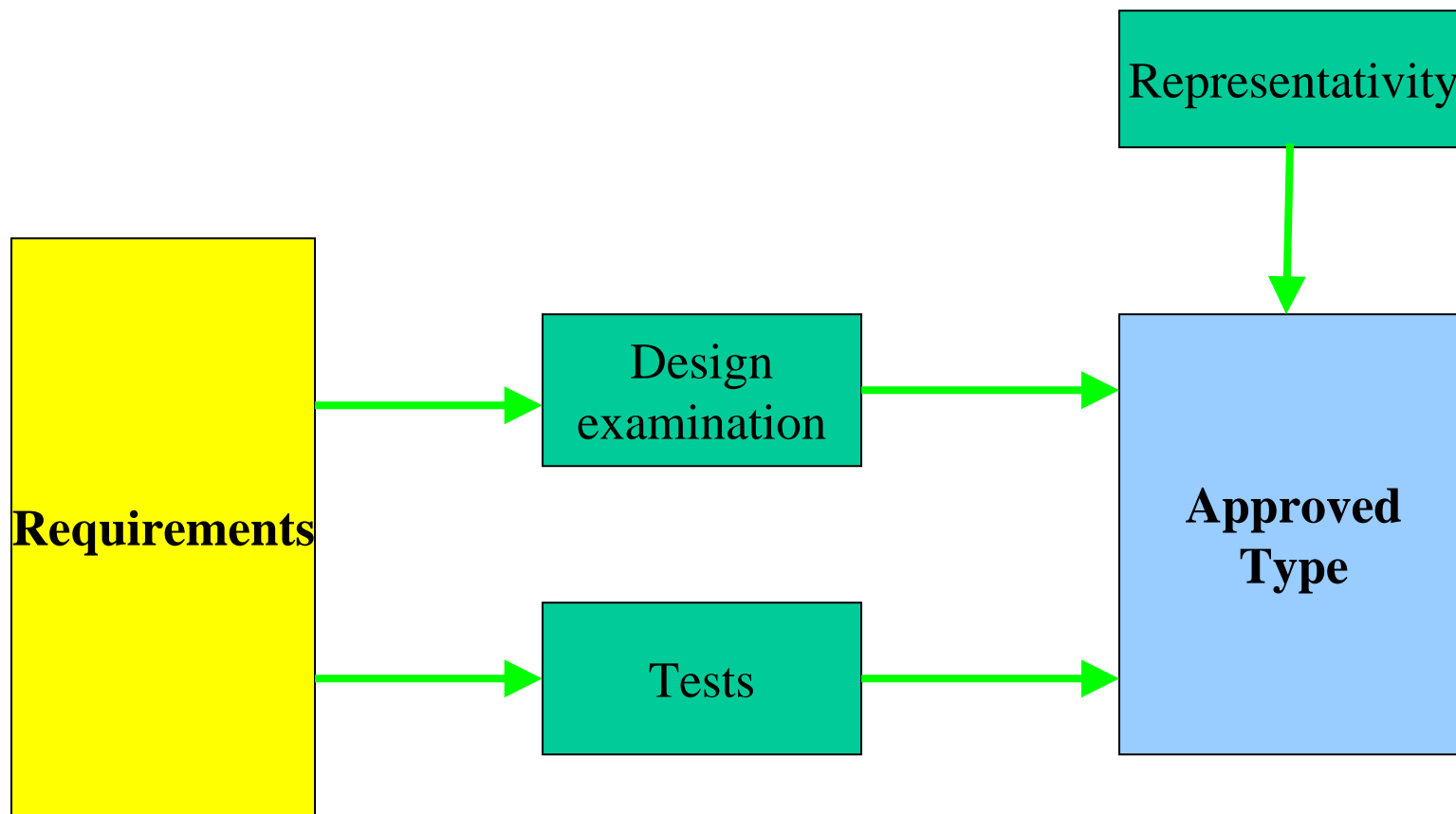


Type approval process

Type approval process includes:

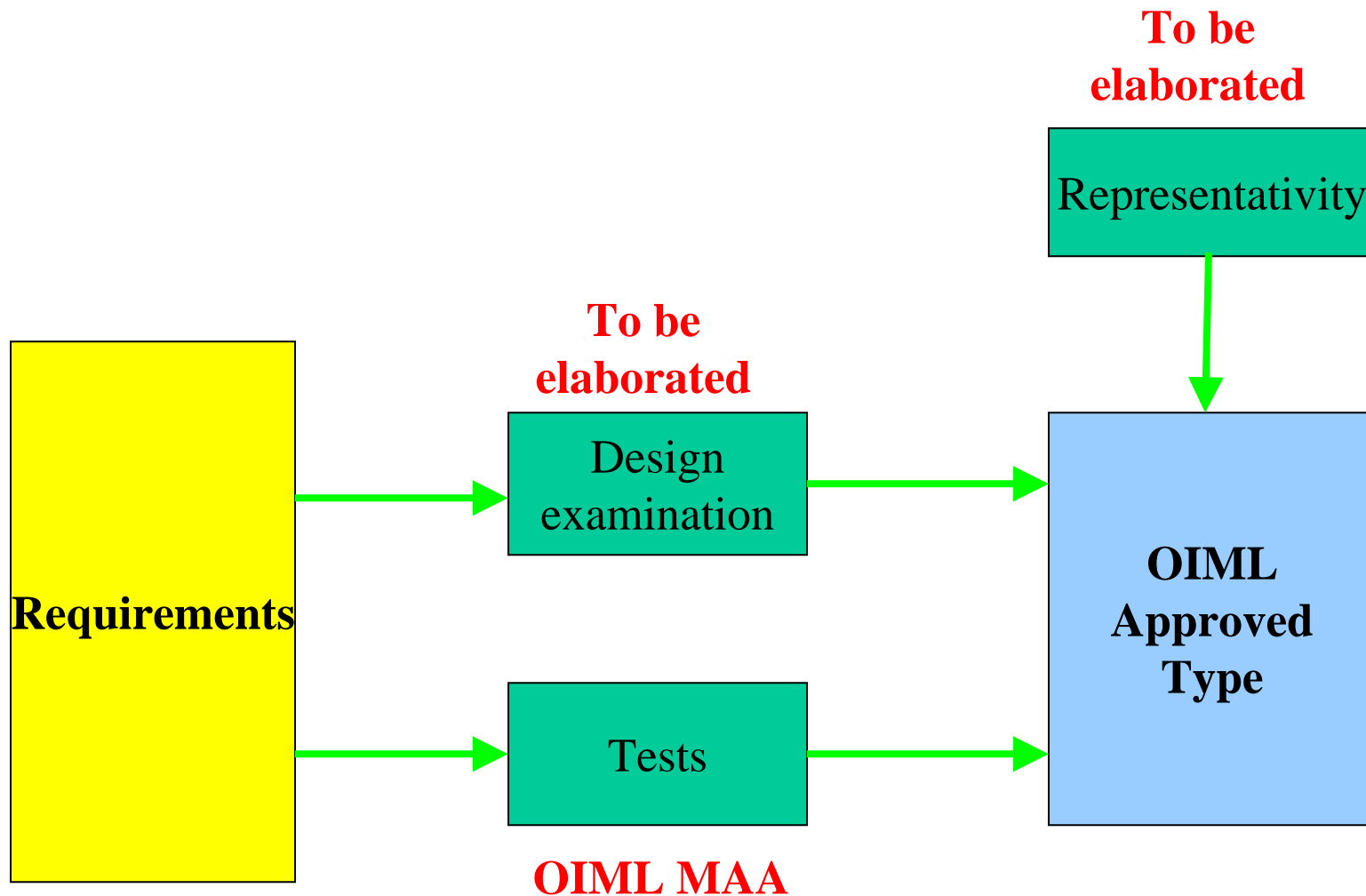
- examination of the representativity of the type
- design examination (compliance examined based on the design documentation)
- tests (compliance examined on a sample of instruments)

Type approval process





OIML systems for Type Approval



Specific and separate procedure:

- Aims at giving confidence and reasonable evidence that instruments produced comply with the approved type
- Inherited conformity is deemed to be satisfied by instruments produced
- Should result in a conformity marking which allows the instruments to be placed on the market



Conformity to Type

Conformity to Type requires:

- definition of the approved type (necessary to be referred to),
- assessment of the quality system of the manufacturer,
- periodical reassessment of this quality system,
- product audits, unexpected, at the occasion of which compliance with type requirements may be verified on a product.



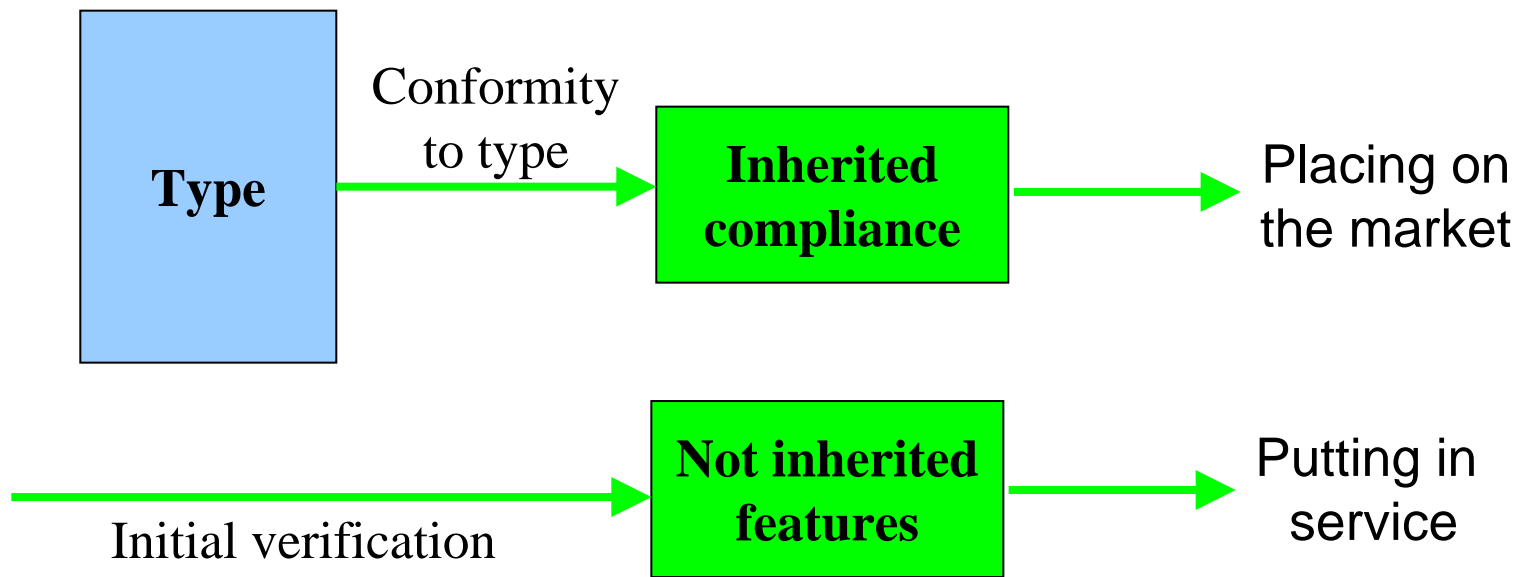
Initial verification

Does not address conformity to type

Addresses compliance of not inherited features

Results in a validity mark

Allows putting the instruments in service



Metrological Control in Developing Economies in Africa

**Presented by
Stuart Carstens**

**Round Table on Metrological Control, CIML meeting,
Mombasa, Kenya,
October 2009**

Contents

- Metrological Control
- Total System Approach
- Pre vs Post market
- State vs Private
- Competence
- MPE's
- Conclusion

Metrological Control

- **Pattern Approval**
- **Verification**
- **Inspection (metrological supervision)**
- **Traceability of measurements**

Total systems approach

- Can apply to prepacked goods
 - Control of instruments used for internal to control
 - Approve test procedures
 - Verify process control records
 - Verify sample
 - Planned inspections vs ad hoc

Total systems approach (cont..)

- Form bases of an MAA to give effect to:
 - WTO obligations/goals
 - Increased market access
 - Removal of TBT's
 - Principle of one test one time one place
- **This approach has benefits to developing and developed economies as goods being imported will comply and therefore resources can be more effectively used**

Total systems approach (cont..)

- Not for instruments used to make measurements at time of sale
 - Consumer needs
 - Reliable; and
 - Accurate measurements
 - Type approval, verification and inspection as acceptable vehicles

Pre market vs post market

Instruments – Pre market

- **Would need**
 - **Technical regulations based on R documents**
 - **Test regime**
 - **Certificates of approval**
 - **Initial verification**

Instruments – Post market

- **Would need**
 - **Generic requirements for accuracy and protection against influences and disturbances**
 - **Deemed to satisfy requirements for proving compliance (R document)**
 - **Verification regime**
 - **Conformity to type**

Pre market vs post market

Commodities – Pre market

•Would need

- Technical regulations
- Approved procedures
- Quality assurance
- Planned inspections
- Registration of packers
- MAA

Commodities – Post market

•Would need

- Technical Regulations
- Approved procedures
- Ad hoc inspections
- Registration of packers and importers

Pre market vs post market

- Instruments
 - A post market system could work but needs a well resourced LM Regulator
 - As regards developing economies a combination between the two would be preferable
 - Type Approval = Pre
 - Verification = Post
 - Inspection = Post

Pre market vs post market

- Commodities
 - A post market system has its challenges as it would necessitate visiting all retail outlets which is:
 - Inefficient
 - Ineffective
 - Expensive
 - Consumer not adequately protected
 - Batches not clearly defined

Pre market vs post market

- A pre market system has clear advantages namely:
 - Cost effective
 - Efficient
 - Effective
 - Facilitates trade
 - Smaller leaner regulator
 - Protected consumer

State vs Private institutions

Instruments (verification) - State	Instruments (verification) - Private
<p>Would need</p> <ul style="list-style-type: none">•Political commitment•Resources (Financial, personnel, equipment etc)•Legislation•Policies & procedures•Sanctions	<p>Would need</p> <ul style="list-style-type: none">•Political commitment•Resources (Financial, personnel, equipment etc)•Legislation•Policies & procedures•Effective and well resourced and supported regulator

State vs Private institutions (cont..)

Instruments (verification) - State	Instruments (verification) - Private
	<p>Would need</p> <ul style="list-style-type: none">•Consider conflict of interest (verification vs repair)•Approved fee structure (geographical situation)•Accreditation•Stringent requirements in place to control•Increased inspection capability

State vs Private institutions

Instruments (inspection) - State	Instruments (inspection) - Private
<p>Would need</p> <ul style="list-style-type: none">•Political commitment•Resources (Financial, personnel, equipment etc)•Legislation•Policies & procedures•Sanctions	<p>Would need</p> <ul style="list-style-type: none">•Political commitment•Resources (Financial, personnel, equipment etc)•Legislation•Policies & procedures•Effective and well resourced and supported regulator

State vs Private institutions (cont..)

Instruments (inspection) - State	Instruments (inspection) - Private
	<p>Would need</p> <ul style="list-style-type: none">• Approved fee structure• Accreditation• Stringent requirements in place to control <p>• Sanction powers will not be delegated but will remain with the regulator</p>

Competence

- Achieving & maintaining competence
 - Need recognized training institutions
 - Currently only In-house training
 - Accreditation
 - Establishment of self-learning modules
 - RLMO's
 - DAM and NWML
 - BIML

Competence

- Developed economies could consider supplying trainers for developing economies
 - Possible data base on OIML website or
 - On RLMO website
 - Donor organisations can source these experts

- Developing economy perspective
 - Only need verification mpe and in-service inspection mpe
 - Definition of traceability requires an uncertainty statement
 - Uncertainty of measurement in verification needs addressing

MPE's (cont...)

- Uncertainty statement not necessary in verification process as:
 - Verification is a go /no go requirement
 - Mpe's are large enough to cover uncertainties
 - The following is prescribed
 - methods
 - Accuracy of standards
 - Prescribed qualifications

MPE's (cont...)

- This reduces uncertainty to acceptable level for trade
- Repetitive tests not always feasible
- User not interested
- Calculations in all cases would increase costs

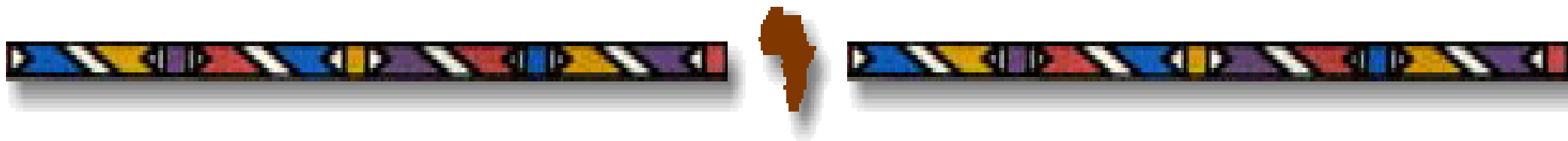
Conclusion

- There is no one approach to metrological control
- Establish a working group to interrogate this issue and recommend a way forward which will suit all economies
- We need to consider the major part of the market ie prepack commodities as opposed to the minor part of the market ie instruments which is well documented

Conclusion

- CIML members become internationally focused and not national or regionally as is the case in many instances
- The support to developing countries needs to explored further
 - Closer ties to donor agencies
 - Training schools (BIPM)
 - Closer cooperation with RLMO's

Thank you for your attention





Metrological control today and in future



Pavel KLENOVSKY
Czech Republic

Definition of the term

Legal metrological control (VIML 2.1): the whole of legal metrology activities which contribute to metrological assurance.

NOTE

Legal metrological control includes:

- legal control of measuring instruments,
- **metrological supervision,**
- metrological expertise.

Metrological control today

Measuring instruments in service – the existing arrangements:

- subsequent verification of legally controlled measuring instruments charged to their users complemented by actions of in-service surveillance as a form of metrological supervision (**the German model**):
 - 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 (consequence: who is to blame for non-compliance in in-situ operations ?)
 - in-situ operations: often made by a sole Government body or agency, at least as regards classical W&M MIs → an ideal impartiality but such body has to work in a harsh environment

Metrological control today

Measuring instruments in service – the existing arrangements:

- subsequent verification of legally controlled measuring instruments charged to their users complemented by actions of in-service surveillance as a form of metrological supervision (**the German model**):
 - network operation possible → the best logistics → the lowest fees
 - an attractive activity for associated businesses (a fee is charged)
 - often accompanied by a high level of servicing operations on the part of repairers

Metrological control today

Measuring instruments in service – the existing arrangements:

- subsequent verification of legally controlled measuring instruments not charged to their users (**the American model**):
 - paid by the Government (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
 - ideally impartial and relatively non-intrusive for users (until the Government has the money to support it)
 - no up-front servicing is applied → the history of metr. performance can be traced back (is not lost)

Metrological control today

Measuring instruments in service – the existing arrangements:

□ metrological supervision (the Dutch model):

- no subsequent verifications in regular intervals are made by force of legislation
- users are solely responsible for compliance of their instruments with the regulations in place and free to take any measures to achieve that
- the most non-intrusive (liberal) to **users** of MIs

Metrological control today

Prevailing problems:

- the German model - a pressure on the part of repairers (mostly authorized representatives of manufacturers) to take over subsequent verification in the area of in-situ operations (classical W&M)
- if performed by a Government agency only (in case of high level of servicing with flexible econo-org.rules) there are the following benefits:
 - an ideal third party – the only way how to prevent manipulation with errors within MPEs
 - ideal logistics – the lowest possible and the same fees for all the users
 - the cheapest solution for the state budget
 - supervision over authorized bodies not effective
 - after all, subsequent verification is not a common business activity

Metrological control in future

At present 2 problems in putting instruments on the market (doubtful effectiveness):

1. conformance to the essential requirements – gold-plated MIs
2. conformance to the approved type – to be made by somebody else than the manufacturer is simply not practical (but an impartiality problem)

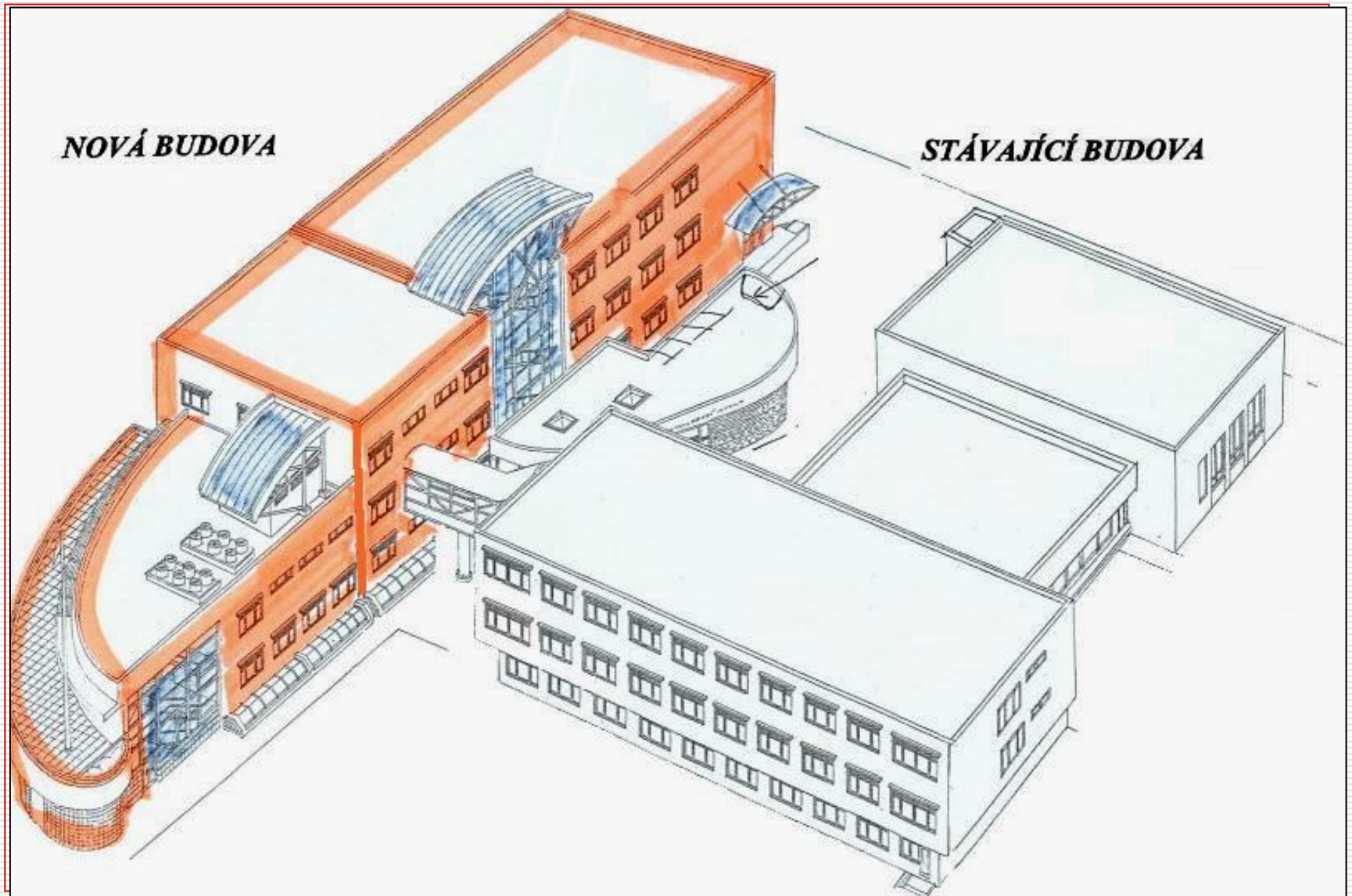
Post-market approach:

- to transfer the core of activities to the in-service stage
- to relax pre-market controls (recognition of tests made by manufacturers) and to strengthen post-market controls: metrological supervision + subsequent verification (if existing) **made by impartial, third-party bodies** (no repairers, no authorized representatives of manufacturers)

Revision of D 16

- responsible TC3/SC2, secretariat: Czech Republic
- now (after 2.5 years) in 3rd CD being voted on to become a Draft Document
- 9 positive votes and 1 abstention out of 17 P-members (the quorum is 12)
- votes from the following P - members are still missing and urgently sought: Australia, Bulgaria, China, France, Romania, Russia, South Africa

Recent developments



Recent developments



Recent developments



THANK YOU FOR YOUR ATTENTION !



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European Cooperation in Legal Metrology

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Content of the presentation


- **General information about European approach**
- **respective role and obligations of**
 - **Member states**
 - **Manufacturers**
 - **Notified bodies**
 - **and again Member states**

EU approach : principles

- 
- **For regulated uses instruments shall satisfy essential requirements before being legally put into service and into use**
 - **Conformity to these requirements is established by mean of conformity evaluation procedures (in most cases one module at the design stage and one at production)**
 - **These procedures involve some activities by notified bodies**
 - **Instruments bear CE marking and supplementary metrology marking M with year of affixing**
 - **OIML recommendations give presumption of conformity**


EU approach

Role of Member states

- 
- **Member states participate in the drafting of directives with the European Commission and in their adoption by EU Parliament and Council**
 - **Member state shall transpose directives in their national legislation**
 - **Member states shall apply the requirements of the directives starting with the criteria for notification of bodies (accreditation has a growing role)**


EU approach

What are the duties of manufacturers ?

- 
- **Manufacturers before putting instruments on the market and in use shall have them certified**
 - **Manufacturers have to prepare the technical documentation describing instrument, including their own tests results and how to ensure conformity during production**
 - **They choose the evaluation procedure among the possible ones (depending on category and technology, choice always possible between Quality assurance and certification by independent body)**
 - **They choose the notified body (there might be one body for certification of type and another one for Quality system)**


EU approach

What are the duties of manufacturers ?

- 
- **The manufacturer provide the chosen notified bodies with the necessary information and inform about modifications**
 - **They have to ensure that instruments in production are in conformity with the certified type, apply the CE and M marking and draw up a declaration of conformity**
 - **They have to provide copy of declaration of conformity and documentation necessary for repair and further verification to users**


EU approach

The notified bodies

- 
- **« Notified » means bodies are designated by Member States to perform a specified activity for a special category of measuring instrument**
 - **They have to fulfill the criteria defined in the directive (competence, independance, accreditation has a growing role)**
 - **They have apply correctly the procedure they are notified for**


EU approach

The notified bodies

- 
- **The notified bodies activity is described in the directive, they examine documentation, evaluate application, instruments and quality system and take final decision which is laid down in a certificate**
 - **Their responsibility is limited to the task they have to perform (they are not responsible for conformity to type which is strictly the responsibility of manufacturers)**

EU approach

Again Member states

- 
- **Member States** have to accept free circulation and free putting into use of EC certified measuring instruments
 - **But they are responsible that the directives are correctly implemented which leads to surveillance activities and they have to exchange information**
 - **Surveillance of the activity of notified bodies**
 - **Market surveillance (2008 European Regulation)**
 - **Surveillance that manufacturers fulfil their duties and that instruments are in conformity (acompanying documents, conformity to type and essential requirements) and that EC marking is correctly applied**

EU approach



Again Member states

- **They have to ensure that instruments in service continue to perform correctly and are correctly used**
- **No common EU approach (except maximum permissible errors and exchange of information)**
- **Possible influence of Service directive for acceptance of bodies from one country to work in another country**

Guides from WG 8 referenced on the EC webpage

- **8.0 general on assessment and operation of NB (applicable standards and link with other guides from the serie)**
- 8.2 Application of module H1
- 8.3 Application of module B
- 8.4 Application of module D
- **8.5 Evaluation of NB for type examination (based on EN 45011)**
- 8.6 Presumption of conformity of QS for modules D and H1, based on EN ISO 9001
- **8.7 Evaluation of NB for module F (based on EN 17020)**
- 8.11 to 8.20 (tables of correspondence between OIML and MID)

All these guides use QA standards with explanation linked to application of directives

WELMEC

European cooperation in legal metrology



Merci de votre attention

Please visit

www.welmec.org



Evolution of Legal Metrology

J.F. Magaña
BIML Director



Starting point

Measurement results

