



Combined R 49/R 60/R 76 CPR Meeting

17-18 June 2009

Federal Office of Metrology METAS - Switzerland

-- M I N U T E S --

- 1 Welcome and opening addresses by the CPR Secretariat**
- &**
- 2 Welcome and opening addresses by the hosting country**
- &**
- 3 Opening of the meeting**

Mrs. Régine Gaucher, CPR Secretariat, welcomed the participants and thanked METAS for its invitation, in particular Dr. Philippe Richard and Mrs. Beatrice Steiner for their cooperation and assistance in the organization of the CPR meetings.

She also welcomed new CPR Members:

- Mr. Alexander Winchester who replaces Mr. Terry Lancaster as the representative of Australia in the R 49 CPR;
- Dr. Grahame Harvey who replaces Mr. Adrian Caster as the representative of Australia in the R 60/R76 CPR;
- Mr. Kazuo Neda who replaces Mr. Fujima as the representative of Japan in the R 76 CPR;
- Mr. James Truex who replaces Mr. Steve Patoray as the representative of the United States in the R 60 CPR;
- Mr. John Barton who replaces Mr. Steve Cook as the representative of OIML TC 9 in the R 60 CPR.

19 CPR Members were in attendance, but Mrs. Gaucher indicated that she had received apologies from:

- Mr. Starev from Bulgaria;
- Mr. Saled Althanyan who replaces Mr. Alaya as the representative of Saudi Arabia in the R 60 and R 76 CPR;
- Mr. Djuric and Mr. Sovric from the Republic of Serbia;
- Mr. Ivan Chren from Slovakia;
- Mr. Butcher as representative of OIML TC 9 in the R 60 CPR;
- Mrs. Lieu from Viet Nam;
- Mr. James Welsch from Canada who was represented by Ms. Nathalie Dupuis-Desormeaux;
- Mr. Moller Nielsen from Denmark;
- Mr. Reader Harris as representative of OIML TC 8/SC 5 in the R 49 CPR.

ANNEX I

List of participants in the meeting

List of Participants - Combined R 49/R60/R 76 CPR Meeting

Members	Country	CPR
Mr. Alex Winchester	Australia	R 49
Dr. Grahame Harvey	Australia	R 60/R 76
Ms. Nathalie Dupuis Desormeaux	Canada	R 60/R 76
Mr. Gilles Vinet	Canada	Observer
Mrs. Corinne Lagauterie	France	R 60/R 76
Dr. Oliver Mack	Germany	Observer
Dr. Koichi Nara	Japan	R 60
Mr. Kazuo Neda	Japan	R 76
Mr. Kim Sung Wook	Republic of Korea	R 76
Mr. Cock Oosterman	The Netherlands	R 60
Mr. Pieter van Breugel	The Netherlands	R 76
Mr. Zhang Yue	P.R. China	R 60/R 76
Mr. Jaco Marneweck	South Africa	R 60/R 76
Mr. Hennie Ferreira	South Africa	Observer
Mr. Hugo Bissig	Switzerland	R 49
Mr. Christian Wuethrich	Switzerland	R 60
Mr. Paul Dixon	United Kingdom	R 49/R 60/ R 76
Mr. James Truex	United States	R 60
Mr. John Barton	OIML TC 9	R 60
Mrs. Corinne Lagauterie	OIML TC 9/SC 1	R 76
Prof. Roman Schwartz	OIML TC 9/SC 1	R 76
Dr. Charles Ehrlich	OIML TC 3/SC 5	R 49/R 60/R 76
Dr. Philippe Richard	Switzerland	
Mr. Gulian Couvreur	Switzerland	Observer
Ms. Régine Gaucher	BIML	R 60/R 76
Mr. Samuel Just	BIML	R 49

ANNEX II

**Reminder of the resolutions relating to the MAA implementation
and the OIML *Basic* Certificate System
which were adopted at the 43rd CIML Meeting**



Item 5 of the agenda

**Reminder of the resolutions
related to the OIML MAA
and
the OIML *Basic Certificate System***

**43rd CIML Meeting
Sydney, Australia**



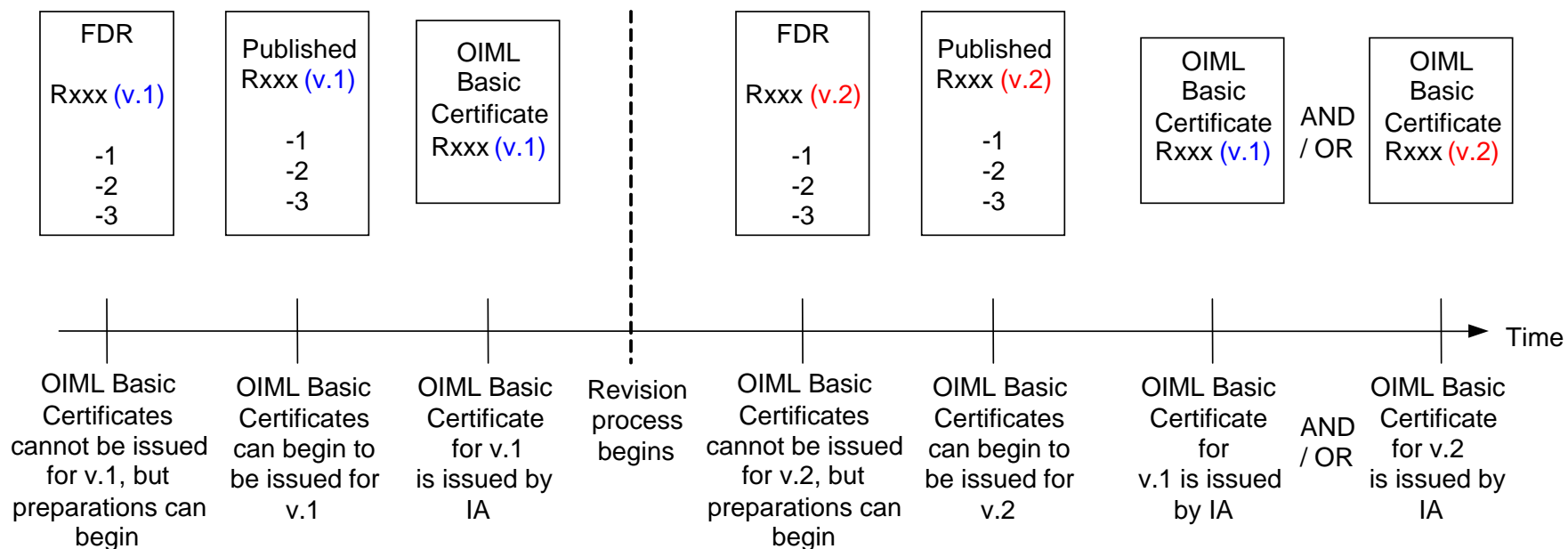
CIML Resolution no. 18

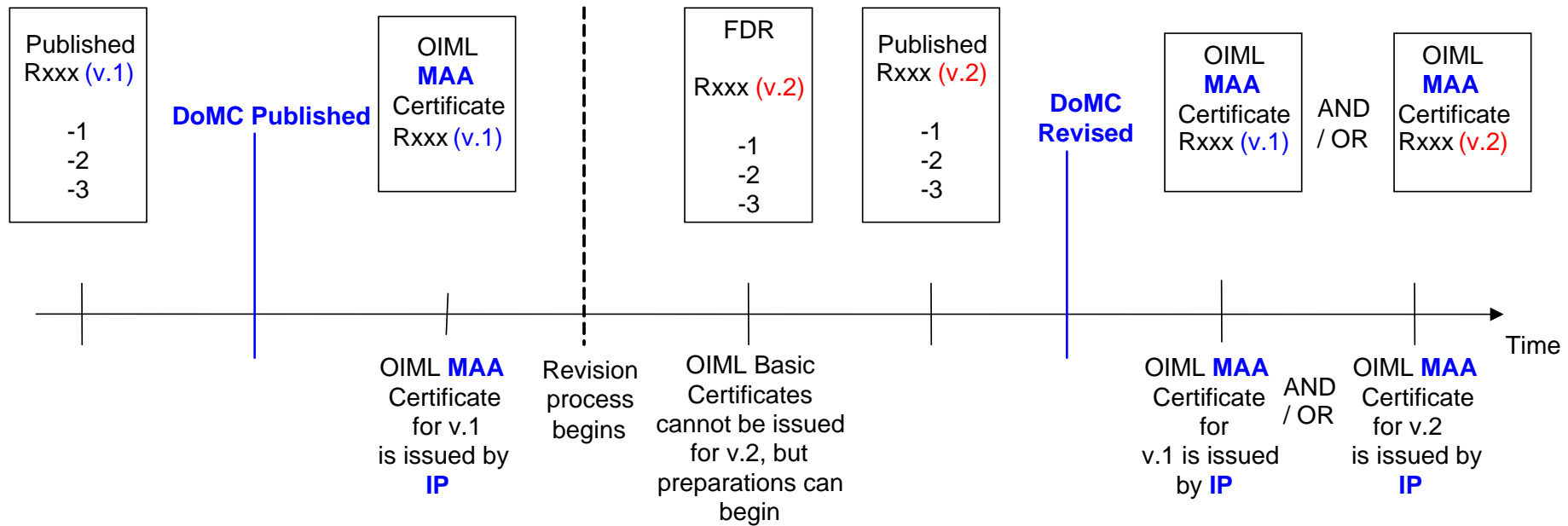


A Draft OIML Publication approved by the Committee shall be available on the OIML web site immediately after approval, for reference purposes and in order for manufacturers and OIML Issuing Authorities to begin preparing for issuing Certificates in the future. However it is not permitted to issue an OIML Basic Certificate based on the Draft.

The official date from which an OIML Basic Certificate can be issued is the date on which the OIML Publication appears on the OIML web site. This date shall be recorded in the table of Publications available on the OIML web site.

The date from which an OIML MAA Certificate can be issued is specified in the corresponding DoMC.







CIML Resolution no. 18

Related actions



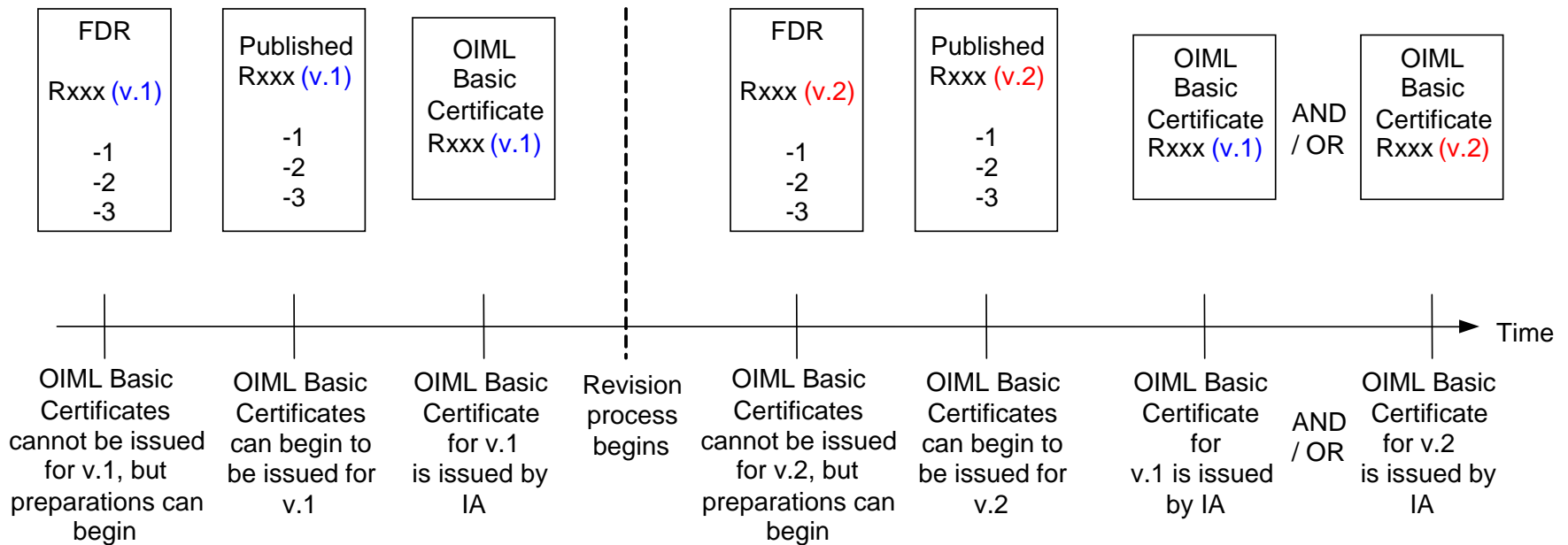
- Web page **to be added** to upload Draft Publications as soon as they are approved by the CIML
- A column “Uploaded” **has been added** to the table of [OIML Publications](#) on the web site
- [Revised R 76 DoMC](#) **has been published**

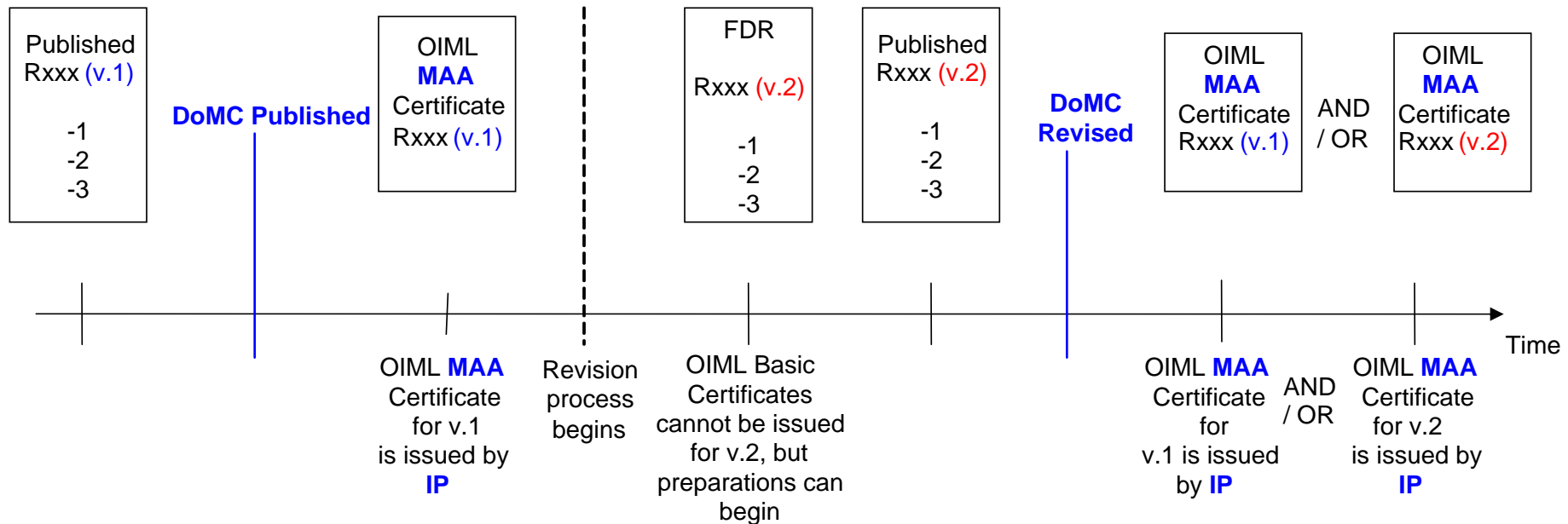
As soon as an OIML Recommendation, including the Test Report Format is published, the relevant OIML Recommendation is automatically included in the OIML Basic Certificate System. The Bureau will publish the appropriate information on the web site

If a new version of an OIML Recommendation is published, the earlier version is maintained in the OIML Basic Certificate System or in the relevant OIML DoMC, together with the new version

A comparison document between the two versions, drawn up by the appropriate TC/SC Secretariat, is no longer required

Note: The last part of the Resolution results in withdrawing the requirement defined in 6.6.1 of OIML B 3: 2003.







CIML Resolution no. 19

Related actions



- *List of categories on the web site under the heading “OIML Certificate System” is updated as soon as a Recommendation which includes a Test Report is published – **Not yet implemented***
- *For a given category, two OIML Recommendations may be listed under the heading “OIML Certificate System”: the current edition and the previous one (e.g. OIML R 76:1992 and OIML R 76:2006) – **Not yet implemented***



CIML Resolution no. 20

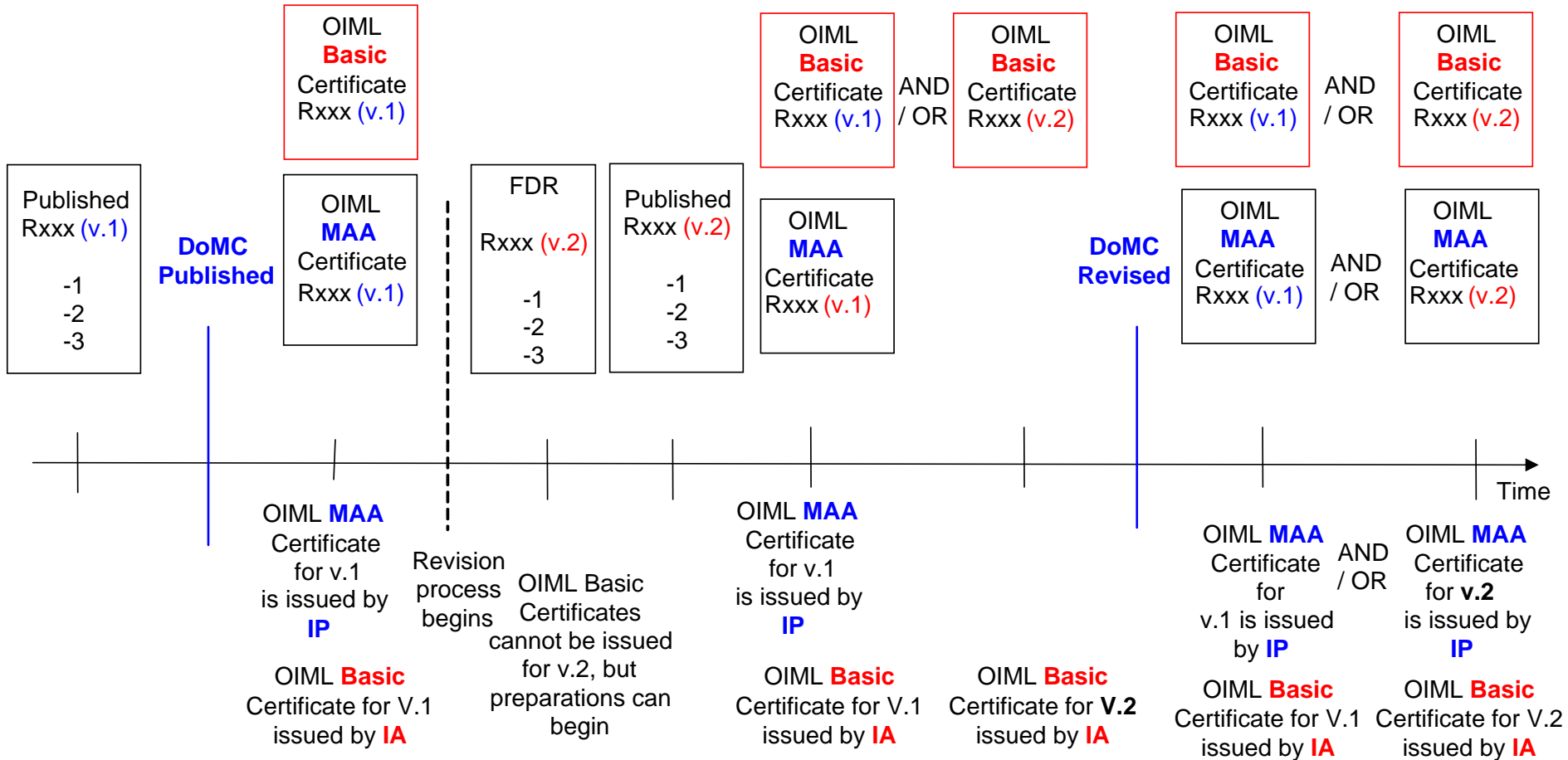


The OIML Basic Certificate System and the OIML MAA are maintained in parallel for categories under the MAA until the Committee decides to stop the implementation of the OIML Basic Certificate System. The proposal to stop the OIML Basic Certificate System for a particular category shall be examined, as appropriate, by the Committee independently for each category covered by the MAA. A two-year period (after the Committee decision) shall be allowed before stopping the OIML Basic Certificate System for the relevant category

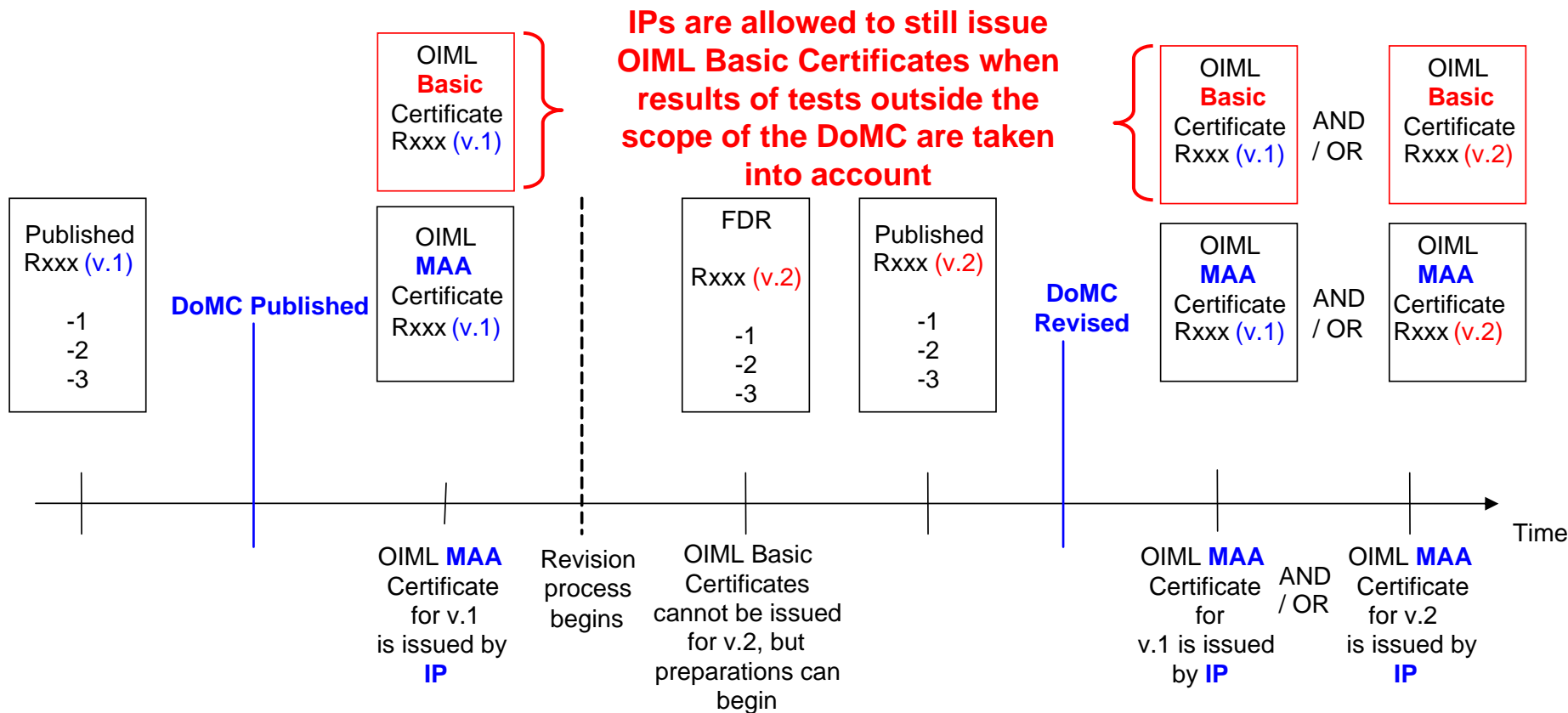
For the time being, Issuing Participants shall not issue OIML MAA Certificates in the event that results of tests outside the scope of the DoMCs are taken into account (e.g. test results from manufacturers) in the Evaluation Reports. In this case an OIML Basic Certificate may still be issued as long as the MAA does not provide this possibility

The Committee supports the intention of TC 3/SC 5 to further discuss the acceptance of manufacturers' test results, with the aim of ultimately including them in the scope of the MAA if consensus can be reached on the conditions to be applicable to manufacturers ISO/IEC 17025 test laboratories.

Application before the OIML Basic Certificate System is stopped



Application to Issuing Participants before and after the OIML Basic Certificate System is stopped





CIML Resolution no. 20

Related actions



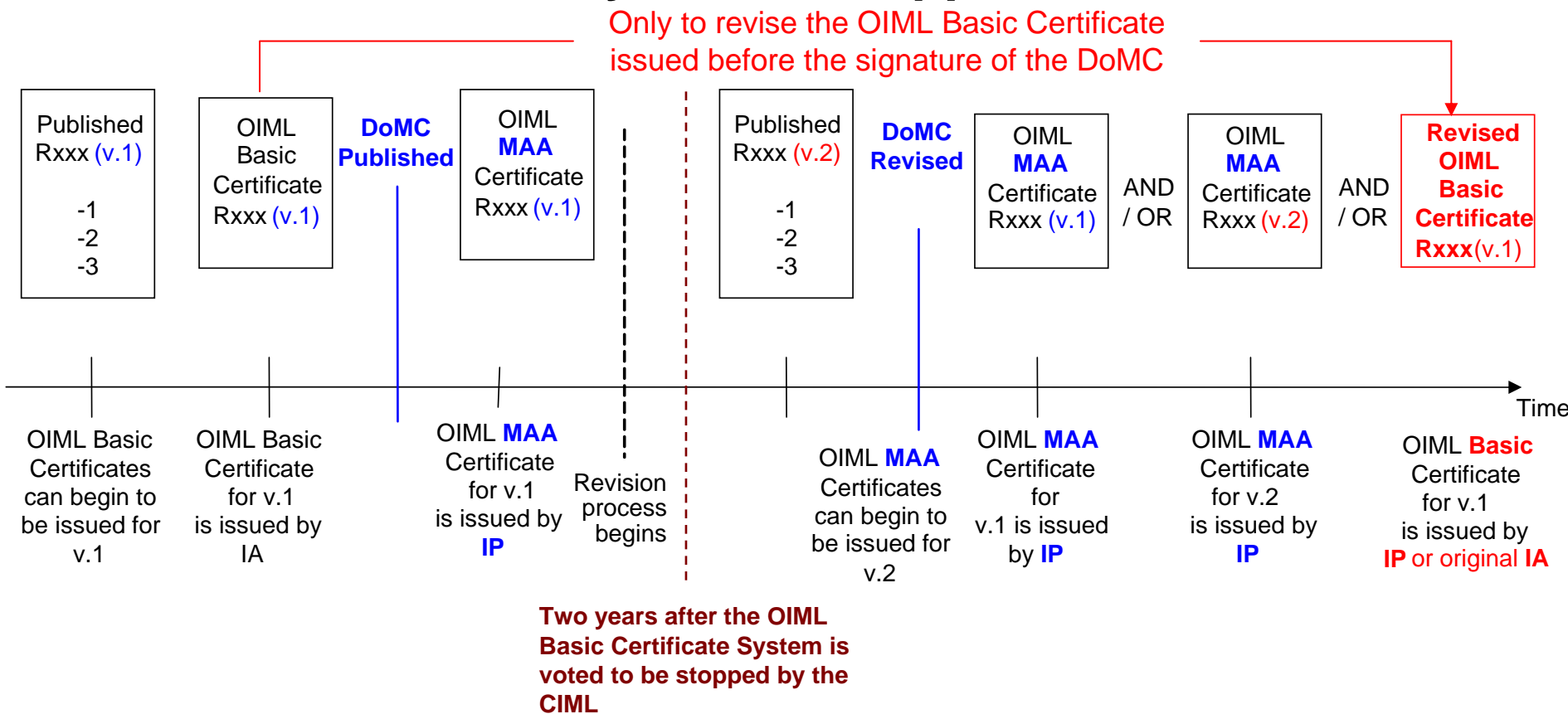
- An Issuing Participant in the R 49, R 60, and R 76 Declarations of Mutual Confidence is allowed to still issue OIML *Basic* Certificates of Conformity in the event that it uses test results provided by manufacturers to assess the conformance of the instrument to the OIML requirements
- Discussions at this meeting under item 7 and 10 of the agenda
- Further discussions at the next TC 3/SC 5 meeting

After the OIML Basic Certificate System for a particular category of instrument has been stopped, when an applicant requests a revision (see the Note below) of an OIML Basic Certificate based on the same version of the OIML Recommendation, which has been subsequently covered by the MAA, the revised OIML Basic Certificate may be issued by the original OIML Issuing Authority even if it is not an Issuing Participant in the relevant DoMC, or by an Issuing Participant in the DoMC

Also after the OIML Basic Certificate System for a particular category of instrument has been stopped, if a new Certificate is applied for, based on the new version of the OIML Recommendation, then an OIML Basic Certificate cannot be issued any more. Rather, an OIML MAA Certificate shall be issued. Therefore the application can only be made to an Issuing Participant in the relevant DoMC

Note: A Certificate is considered to be a 'revision' when the basis for issuing the revised Certificate is the same edition of the Recommendation as was used when issuing the original Certificate. A Certificate is considered to be 'new' when the Certificate is issued on the basis of the new version of the Recommendation, even if some results of tests conducted when issuing the original Certificate are still valid and used for issuing the new Certificate

Application of the MAA after the OIML Basic Certificate System is stopped





CIML Resolution no. 21

Related actions



No related action at present since the OIML MAA and the OIML *Basic Certificate System* are maintained in parallel for OIML R 60, R 76 and R 49

ANNEX III

**Reminder of the conclusions
of the OIML TC 3/SC 5 meeting
held in May 2008 in Paris**



Item 6 of the agenda

Reminder of the main conclusions

OIML TC 3/SC 5 meeting

May 2008

Paris, France



Revision of OIML B 3

- 1CD was discussed at the meeting
- New title: OIML *Basic* Certificate System for OIML Type Evaluations
- Introduction to be added to emphasize that the OIML B 3 defines general requirements to which OIML B 10 provides additional or other requirements for the implementation of the OIML MAA (same contents in both Publications)



Revision of OIML B 3

- Scope: to be modified to clarify that conformity to type is not addressed in OIML B 3
- Revision of the terminology to be consistent with OIML B 10
- Designation of OIML Issuing Authorities: still under the responsibility of CIML Members but evaluation by CIML Members will be clearly required

- Clarification of the contents of Evaluation Reports and test reports
- Clarification of issues related to the revision, transfer of *Basic* Certificates
- Several editions of an OIML Recommendations in the OIML *Basic* Certificate System
- No period of validity of *Basic* Certificates



Revision of OIML B 3

2CD

**based on TC 3/SC 5 meeting conclusions
should be circulated for comments
within TC 3/SC 5 Members
by the end of September 2009**

- **OIML B 10-2 will be withdrawn due to the publication of OIML D 30**
- **OIML B 10-1 will be renamed OIML B 10**
- **Reference to ISO/IEC Guide 65 to be deleted**

- **Operating rules of the CPRs to be revised (e.g. voting rules in case of more than one Participant in a DoMC per country)**
- **Conditions for designation of a new Issuing Authority for a category under a DoMC**

1CD

**based on TC 3/SC 5 meeting conclusions
should be circulated for comments
within TC 3/SC 5 Members
by the end of September 2009**



OIML TC 3/SC 5 project p2

1CD circulated for comments
by 15 September 2009
within TC 3/SC 5

ANNEX IV

**Type approval test results
provided by manufacturers of measuring instruments**

4th CPR meeting, 17-19 June 2009

Use of Test Results from Manufacturers' ISO/IEC 17025 Test Laboratories (MTLs) within the Scope of the OIML Mutual Acceptance Arrangement (MAA)

Roman Schwartz

Physikalisch-Technische Bundesanstalt (PTB), Germany

Use of Test Results of MTLs under the OIML MAA

1. Background and Motivation

Roman Schwartz

2. Report about the Peer Assessments at Sartorius DE and Mettler Toledo CH (20 - 24 April 2009)

- Experiences, Major Results and Conclusions -

Jaco Marneweck

3. WD CPR-05 and Proposals to the CPR

Roman Schwartz

- Discussion -

Background

❖ TC3/SC5, May 2008, Resolution 2008/04:

"... Discussions on the acceptance of manufacturers' test results are still ongoing within OIML TC 3/SC 5. For the time being, Issuing Participants shall not issue OIML MAA Certificates in the event that results of tests outside the scope of the DoMCs are taken into account (e.g. test results from manufacturers) in the Evaluation Reports. In this case an OIML Basic Certificate may still be issued.

Note: Proponents of acceptance of manufacturers' test results will provide an explanation on conditions (in particular to guarantee that the acceptance of manufacturer's test data can be done in a fair manner for all manufacturers) which could be requested to include manufacturers' test results in the implementation of the MAA and an example, to be submitted for CPR examination at the next CPR Meeting (possibly a combined R 60 CPR/R 76 CPR/R 49 CPR Meeting)."

Background (cont.)

❖ Proponents:

- **Germany**
- **Switzerland**
- **United Kindom (at least for accredited MTLs)**
- **Netherlands (at least: keep status quo)**
- **France (at least: support of WELMEC position)**
- **South-Africa ?**
- **?**

Background (cont.)

❖ Examples submitted to CPR:

(1) DE: Application File for DoMC R76, Dec. 2008:

- > Annex G.1: *PTB conditions and assessment procedure concerning the use of test results from MTLs (QM working procedure of PTB)*
- > Annex G.2: *PTB checklist for the assessment of a MTL (in English)*
- > Annex G.3: *PTB checklist of last assessment of Sartorius (17 April 2008)*
- > Annex G.4: *PTB checklist of last ass. of Mettler Toledo CH (14 Oct. 2008)*

(2) DE / CH: Voluntary peer assessments at Sartorius (DE) and Mettler Toledo (CH) according to the MAA rules (B10-2:2004, MAA-01:2005, D30:2008), 21 - 24 April 2009:

- > WD R49/ R60/ R76 CPR - 05 (9 May 2009): *Chapters 2 and 3*
- > Peer assessment report - METTLER TOLEDO testing lab. *(Brian Beard, ZA)*
- > Peer assessment report - SARTORIUS testing laboratory *(Brian Beard, ZA)*

Background (cont.)

❖ 43rd CIML Meeting, Sydney 2008, Resolution No 20:

The OIML Basic Certificate System and the OIML MAA are maintained in parallel ... until the Committee decides to stop the implementation of the OIML Basic Certificate System. ...

For the time being, Issuing Participants shall not issue OIML MAA Certificates in the event that results of tests outside the scope of the DoMCs are taken into account (e.g. test results from manufacturers) in the Evaluation Reports. In this case an OIML Basic Certificate may still be issued as long as the MAA does not provide this possibility.

The Committee supports the intention of TC 3/SC 5 to further discuss the acceptance of manufacturers' test results, with the aim of ultimately including them in the scope of the MAA if consensus can be reached on the conditions to be applicable to manufacturers ISO/IEC 17025 test laboratories.

43rd CIML Meeting, Resolution No 20

⇒ **The CIML unanimously decided that...**

- ... **the two Certificate Systems are maintained in parallel (for the time being)**
- ... **OIML Basic Certificates may still be issued by MAA Issuing Participants if they make use of test results of MTLs, as long as the MAA does not provide this possibility**
- ... **it supports the intention of TC 3/SC 5 to further discuss the acceptance of manufacturers' test results, with the aim of ultimately including them in the scope of the MAA if consensus can be reached on the conditions to be applicable to MTLs.**

43rd CIML Meeting, Resolution No 20

That means:

- ❖ **No more debates on principles, i.e. whether or not we want to use test results from MTLs under the MAA**
- ❖ **But discussion of the conditions to be defined for MTLs under the scope of the MAA!**

Motivation

Why is the issue of MTLs so important for the OIML and the success of the OIML MAA?

- ❖ It touches the liaison of OIML with ILAC and IAF
 - > **OIML - ILAC - IAF MoU (Oct. 2007)**
- ❖ It is one of the reasons why the MAA is by far not (yet) as successful as the Basic Certificate System is since 1991
 - > **Examination and analysis of the OIML certificate data base**
- ❖ It touches the position of OIML towards the quality management efforts of (globally operating) manufacturers
 - > **Misunderstandings and prejudices to be resolved**
- ❖ It is strongly related to the issue of Conformity To Type (CTT)
 - > **No CTT without MTLs, and other QM efforts of manufacturers**

Liaison of OIML with ILAC and IAF

Quotation from the
MoU (Oct. 2007):



MEMORANDUM OF UNDERSTANDING (MOU)
BETWEEN
THE INTERNATIONAL LABORATORY ACCREDITATION COOPERATION (ILAC),
THE INTERNATIONAL ACCREDITATION FORUM (IAF)
AND
THE INTERNATIONAL ORGANIZATION OF LEGAL METROLOGY (OIML)

The aim of the cooperation between ILAC, IAF and OIML is to:

a) maintain an active ILAC-IAF-OIML liaison by:

i) **facilitating common approaches in the interpretation and implementation of ISO/IEC 17025, ISO/IEC Guide 65, ISO/IEC 17021 and other relevant standards and/or technical criteria, and**

ii) **harmonising assessment procedures;**

b) ...

Liaison of OIML with ILAC and IAF

The aim of the cooperation between ILAC, IAF and OIML is to:

...

d) request ILAC and IAF members to use technical and metrological experts and assessors from the above-mentioned lists whenever legal metrology is included in the scope of the accreditation;

e) ...

f) ...

g) request OIML to recognize accreditations delivered under the conditions defined in this MoU

h) promote and develop the consistency and complementarity of the ILAC Mutual Recognition Arrangement, the IAF Multilateral Recognition Arrangement and the OIML Mutual Acceptance Arrangement;

i) promote and develop inter-laboratory comparisons ...

⇒ The exclusion of (accredited) ISO/IEC 17025 MTLs from the MAA is certainly not in line with the aim of the OIML-ILAC-IAF MoU.

Analysis of OIML Certificate Data Base

Source:

> <http://www.oiml.org/certificates/>

Last update:

> 9 June 2009

Analysis:

> Basic Certificates 1991 - 2004

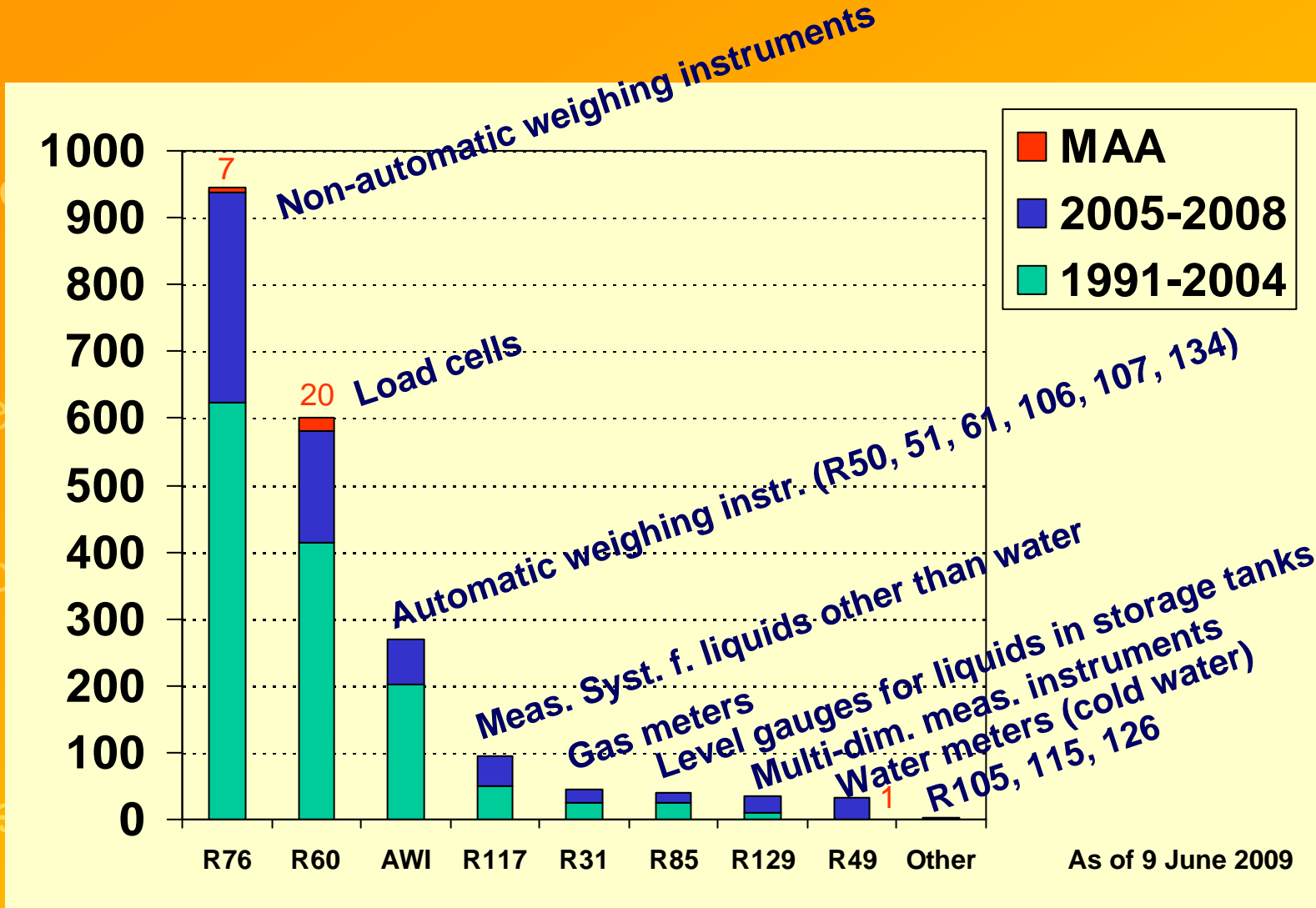
> Basic Certificates 2005 - 2009

> MAA Certificates 2006 - 2009

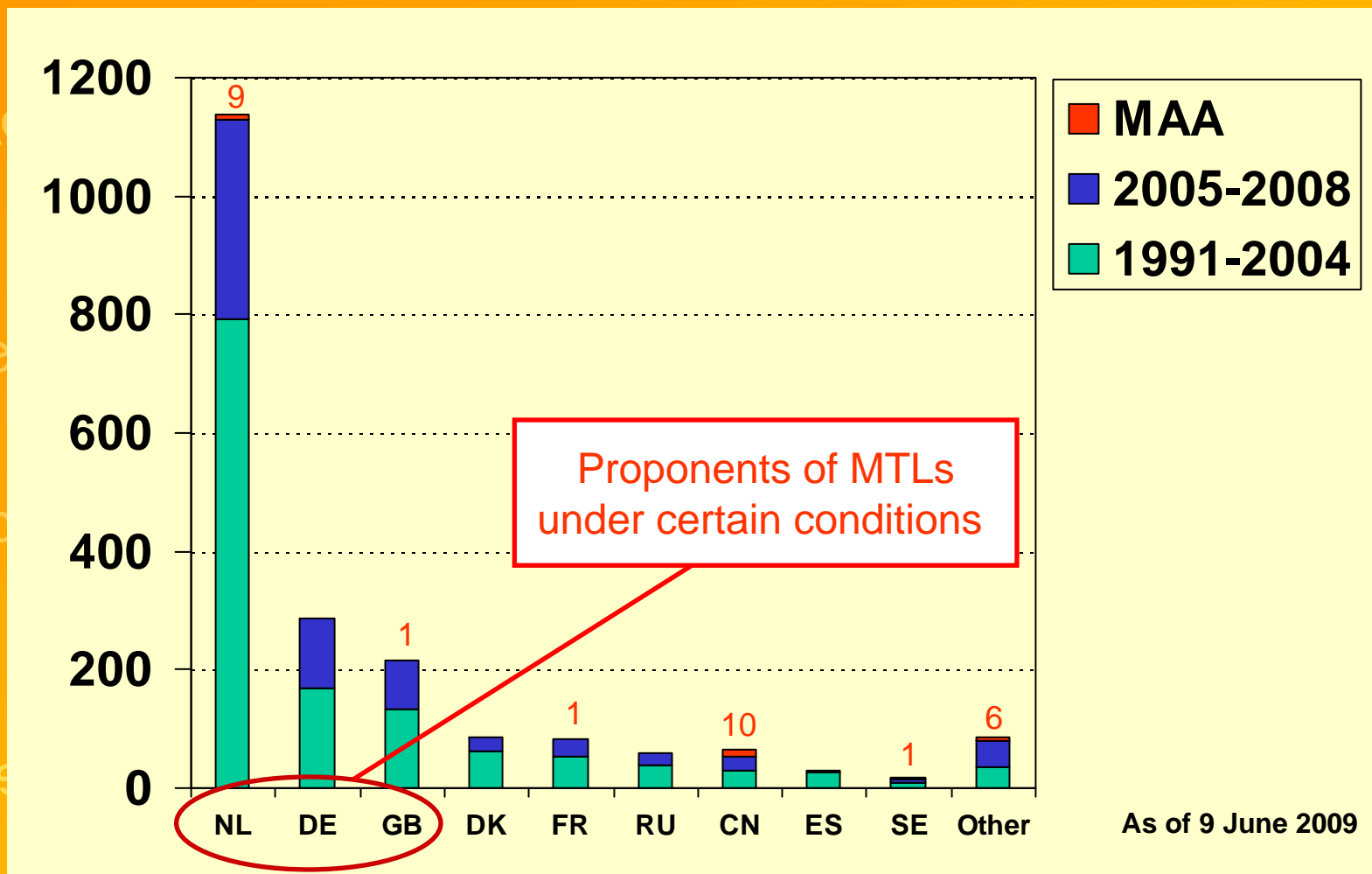
Analysis of OIML Certificate Data Base

- **1348 Basic Certificates 1991 - 2004** (incl. Revisions)
= 96 cert./ a (all) = 74 cert./ a (R60+R76)
- **689 Basic Certificates 2005 - 2009** (incl. Revisions)
= 153 cert./ a (all) = 107 cert./ a (R60+R76)
- **28 MAA Certificates 2006 - 2009** (1xR49, 20xR60, 7xR76)
= 8 cert./ a (all) = 8 cert./ a (R60+R76)
- **16 Categories** (OIML Recommendations) **MAA: 3**
- **21 Issuing Authorities**
MAA: 12 Issuing Participants (2xR49, 7xR60, 9xR76)
- **≈ 500 Manufacturers** (Recipients of Certificates) **MAA: 21**

OIML Certificates (incl. Revisions) / Categories

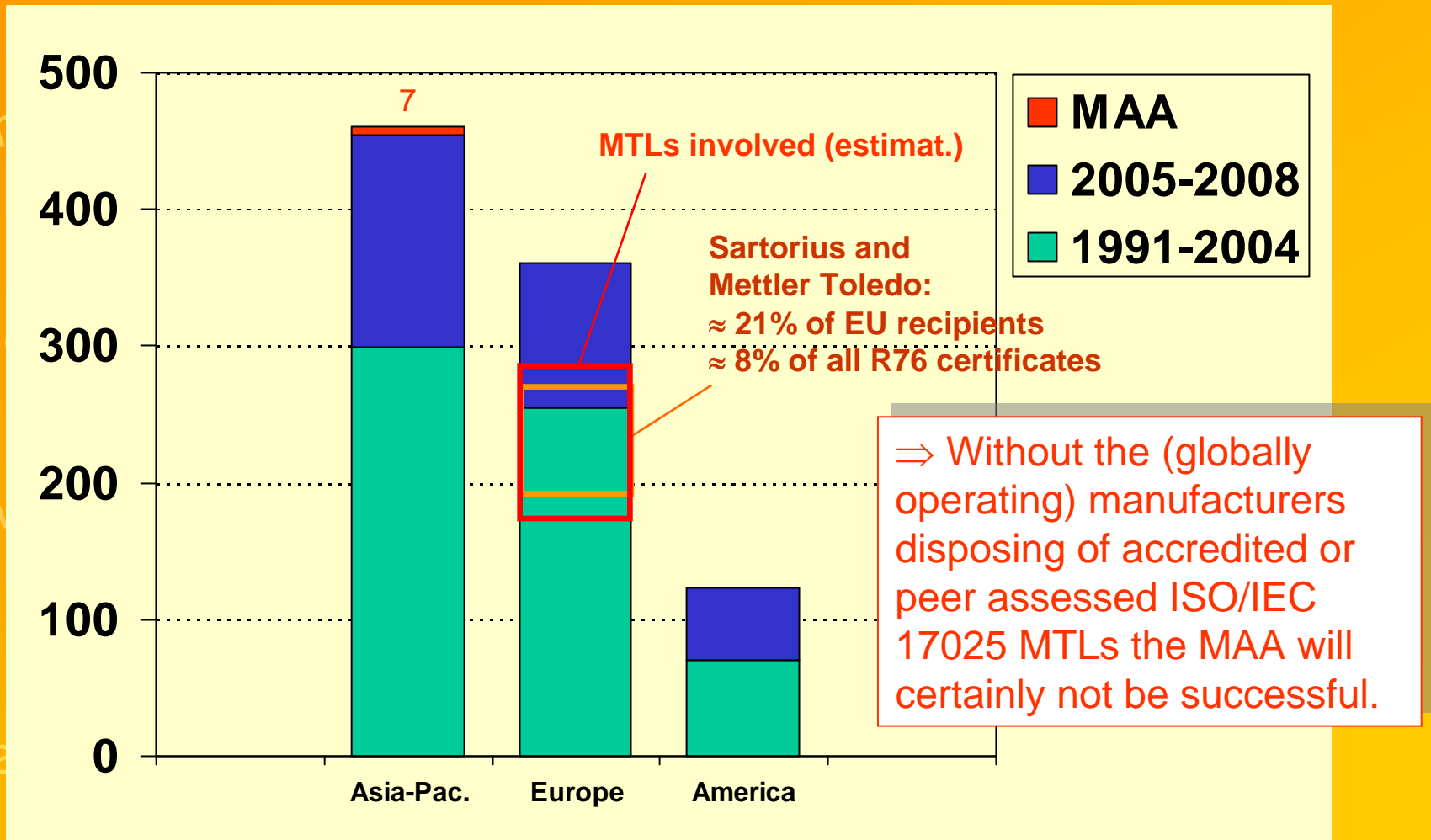


OIML Certificates (incl. Revis.) / Issuing Authorities



R76 Certificates (incl. Revis.) / Recipients in Regions

945 Certificates for NAWIs = 46% of all OIML Certificates:



Misunderstandings and prejudices concerning MTLs

- 1. MTLs and its personnel can never be sufficiently independent nor impartial, i.e. they can never be sufficiently free from undue commercial, financial or other pressures or influences.**

Misunderstandings and prejudices concerning MTLs

1. Reply:

ISO 17025 requirements for testing labs are often mixed up with ISO Guide 65 requirements for certification bodies (Issuing Authorities).

ISO/IEC 17025 primarily aims at the competence of test labs.

Whereas ISO Guide 65 requires the independence of the Issuing Authority that is responsible for the evaluation report and the certificate based on a judgement of the test report supplied by a competent test lab.

Impartiality and independence are mentioned only once in
ISO/IEC 17025:

Misunderstandings and prejudices concerning MTLs

ISO/IEC 17025:2005, No 4.1.4:

If the laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory shall be defined in order to identify potential conflicts of interest.

NOTE 1: Where a laboratory is part of a larger organization, the organizational arrangements should be such that departments having conflicting interests ... do not adversely influence the laboratory's compliance with the requirements of this International Standard.

NOTE 2: If the laboratory wishes to be recognized as a third-party laboratory, it should be able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial and other pressures which might influence their technical judgement. The third-party testing or calibration laboratory should not engage in any activities that may endanger the trust in its independence of judgement and integrity in relation to its testing ... activities.

Misunderstandings and prejudices concerning MTLs

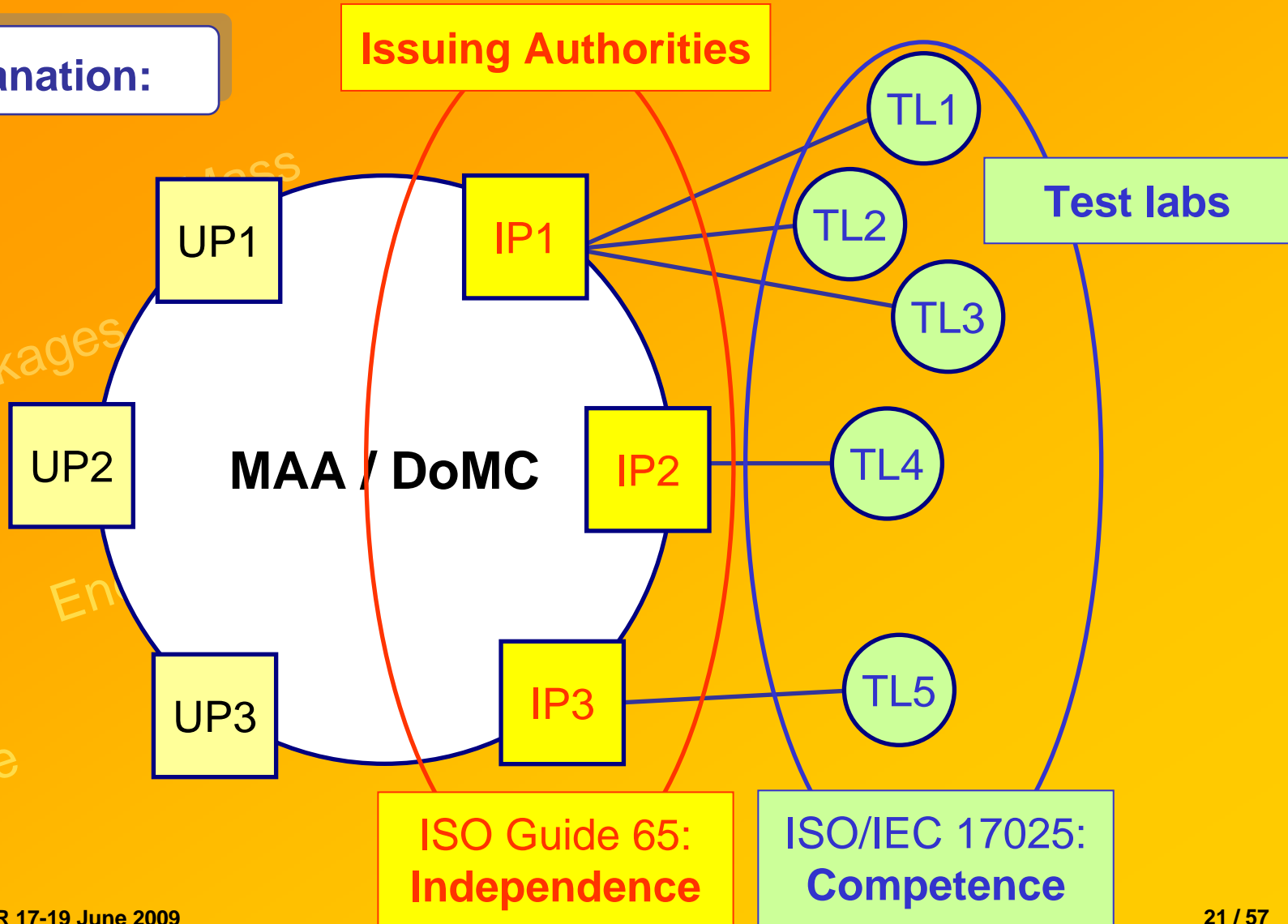
That means,

- firstly, ISO 17025 does not require impartiality (only if the laboratory wishes), and
- secondly, any testing or calibration laboratory can be recognised as a third-party laboratory if certain (QM) conditions are met.

⇒ ILAC accrediters do not have any problems in accrediting private testing laboratories as third-party labs according to ISO/IEC 17025

Misunderstandings and prejudices concerning MTLs

Explanation:



Misunderstandings and prejudices concerning MTLs

- 2. Manufacturers do often not have appropriate test equipment, experience nor competence; they produce (by chance) a "Golden Instrument", test it (or have it tested), let it be certified, and forget about all that when starting and running the (series) production.**

Misunderstandings and prejudices concerning MTLs

2. Reply:

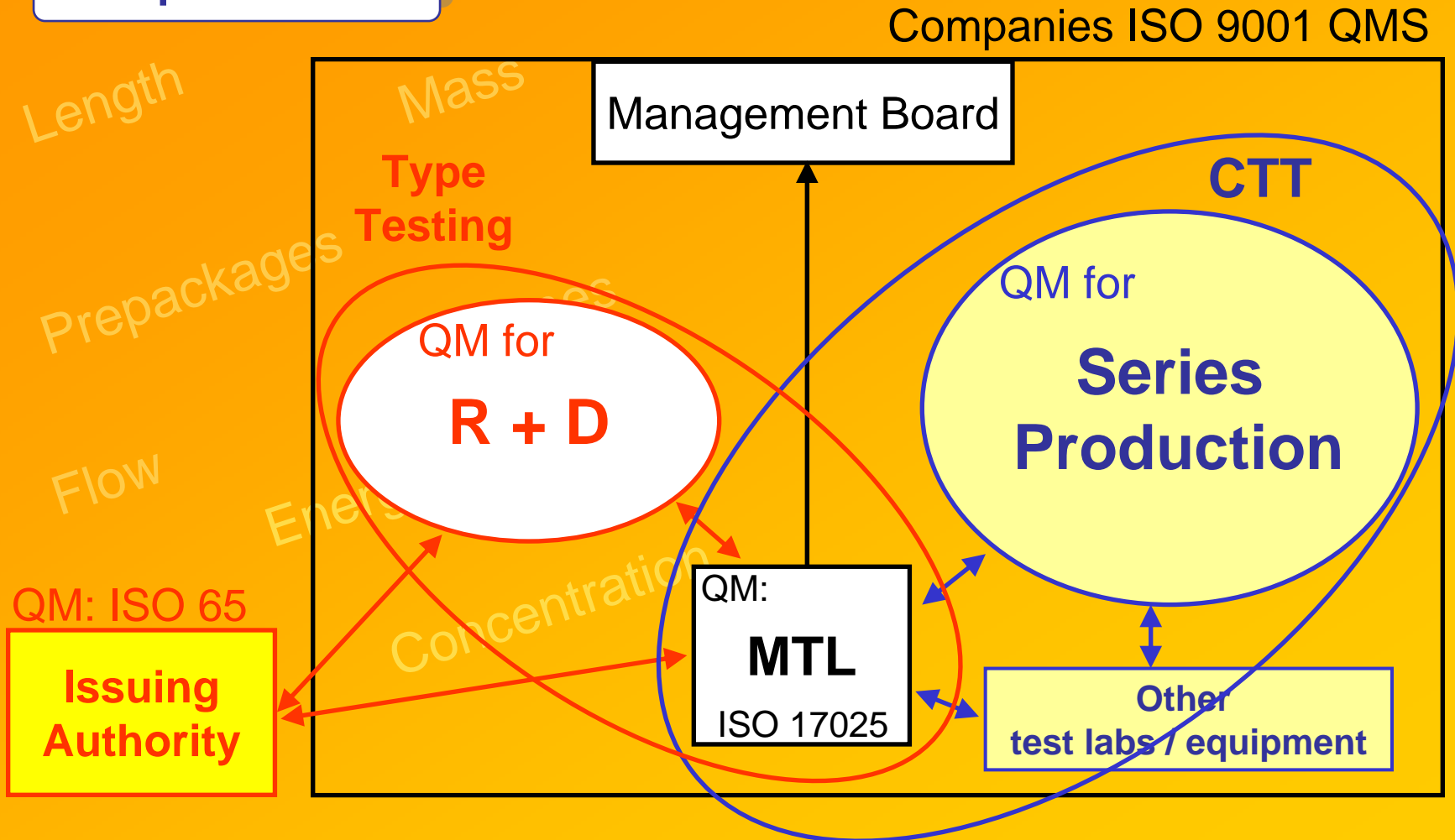
This could be a problem with small companies not having implemented appropriate, acknowledged (e.g. ILAC accredited) and supervised QM systems for R+D, production control, etc.

Globally operating manufacturers, however, do always dispose of very effective, acknowledged and regularly supervised quality management systems (procedures and facilities), normally based on ISO 9001 plus ISO/IEC 17025 for certain areas, such as a testing or calibration labs. These manufacturers have a strong self-interest in having 0% deficient products, because they can survive the international competition only with absolute (100%) production control. They make intensive use of high-quality testing not only at R+D, but also at all stages of the series production.

⇒ **OIML should recognize and support the efforts of manufacturers having implemented very effective QM systems, including MTLs.**

MTLs Relationship with Conformity to Type (CTT)

Explanation:



The peer assessments at Sartorius (DE) and Mettler Toledo (CH), 20 - 24 April 2009

Idea:

- Born at the last TC3/SC5 meeting 2008, BIPM, Sèvres
- With BIML knowledge and support

Objectives:

- Support future discussions both in TC3/SC5 and CPR by a practical example where MAA rules are applied 1:1 to MTLs
- Involve regions outside Europe to facilitate a better understanding of MTLs and an appropriate treatment by OIML
- Facilitate the implementation of Resolution No 20 of the 43rd CIML meeting (conditions to be applicable to MTLs)
- Support the PTB application for the R76 DoMC (step 2)
- Emphasis placed on management & organisational aspects

The peer assessments at Sartorius (DE) and Mettler Toledo (CH), 20 - 24 April 2009

The Peer Assessment Team at Sartorius:



From left to right:

- **Michael Denzel, DE**
(OIML techn. & metrological expert for R76)
- Andreas Odin, DE
(OIML / ILAC / IAF lead assessor, observer)
- Veronika Martens, Sartorius (head MTL)
- Horst Roetteken, Sartorius (coworker MTL)
- Jaco Marneweck, ZA
(CPR member, observer)
- Roman Schwartz, DE
(CIML and CPR member, observer)
- **Brian E. Beard, ZA**
(OIML / ILAC / IAF lead assessor, lead of PA)

Not on the picture:

- Gulian Couvreur, CH
(METAS observer for the peer assessment at Mettler Toledo)

The peer assessments at Sartorius (DE) and Mettler Toledo (CH)

Program (20 - 24 April 2009):

- Day 1:

- Preparation of the two PAs at PTB (without manufacturers)
- Laboratory visits at PTB

- Day 2:

- Visit to Sartorius AG, Goettingen (DE)
- Presentation of the company and its policies by Dr. Maaz, member of the management board of Sartorius
- Assessment of the filled-in B10-2 checklist and other QM documents supplied by Sartorius (together with QM and head of MTL: V. Martens)
- Visit to the accredited calibration laboratories for mass and non-automatic weighing instruments (different from the R76 test lab)
- Visit to the (non-accredited*) R76 MTL * *there is no accr. body yet in Germany*

The peer assessments at Sartorius (DE) and Mettler Toledo (CH)

Program (20 - 24 April 2009) (cont.):

- Day 3:

- Continuation of the PA at Sartorius
- Preparation of the draft PA report by Brian Beard and Michael Denzel
- Visit to the production of precision NAWIs and machining of EMF load cells, including test facilities that ensure full production control (CTT)
- Travel to Greifensee, Switzerland

- Day 4:

- Visit to Mettler Toledo Greifensee / Naenikon (CH)
- Presentation of the company and its policies by Mr. Urs Widmer, member of the management board of Mettler Toledo
- Assessment of the filled-in B10-2 checklist and other QM documents supplied by Mettler Toledo (together with QM responsables of MT)

The peer assessments at Sartorius (DE) and Mettler Toledo (CH)

Program (20 - 24 April 2009) (cont.):

- **Day 4 (cont.):**
 - **Visit to the accredited R76 testing lab. of Mettler Toledo (ISO/IEC 17025)**
- **Day 5:**
 - **Continuation of the PA at Mettler Toledo**
 - **Preparation of the draft PA report by Brian Beard and Michael Denzel**
 - **Visit to the accredited calibration lab. for mass (different from R76 MTL)**
 - **Visit to the production of precision weights, precision NAWIs and machining of EMF load cells, including test facilities that ensure full production control (CTT)**
 - **Travel back to Braunschweig (DE)**

The peer assessments at Sartorius (DE) and Mettler Toledo (CH)

Results / Reports:

> will be presented by Jaco Marneweck:

Use of Test Results of MTLs under the OIML MAA

1. Background and Motivation

Roman Schwartz

2. Report about the Peer Assessments at Sartorius DE and Mettler Toledo CH (20 - 24 April 2009)

- Experiences, Major Results and Conclusions -

Jaco Marneweck

3. WD CPR-05 and Proposals to the CPR

Roman Schwartz

- Discussion -

WD CPR - 05 / Ch. 3: Conclusions of the PA

For each peer assessment a full peer assessment report according to OIML MAA-01 has been completed by the two assessors (Brian E. Beard and Michael Denzel), including the B10-2 checklists (chapter 4).

The complete peer assessment reports, including the B10-2 checklists, have been made available to the CPR members (see CPR website).

The conclusions can be summarised as follows.

WD CPR - 05: Conclusions of the PA (cont.)

(a) The laboratory quality system of both MTLs is according to ISO 17025 and forms part of the overall ISO 9001 quality management system of the mother companies.

Policies and procedures addressing the elements of ISO 17025 and relating specifically to the laboratory are covered in a laboratory management handbook.

WD CPR - 05: Conclusions of the PA (cont.)

(b) Checklists according to OIML B 10-2 were completed by both MTLs and samples of the answers were evaluated for validity during the assessment using the OIML D30 (2008).

Samples of other policies and procedures were also evaluated with aspects of independence from the mother companies and relations with the Issuing Authority (PTB) were concentrated upon.

WD CPR - 05: Conclusions of the PA (cont.)

(c) According to the management structure both R76 testing laboratories are independent of other business units of the mother companies with their heads having direct access to the companies' management or executive boards.

No evidence was found to indicate that the activities of either MTL or its relation to the manufacturing divisions of the mother companies will compromise its independence, judgement, impartiality or operational integrity.

WD CPR - 05: Conclusions of the PA (cont.)

(d) In both cases the quality system was found to be suitable and effective for the activities of the MTL and it was adequately entrenched and maintained.

WD CPR - 05: Conclusions of the PA (cont.)

(e) A few non conformances were found and these are mainly related to lack of policies and procedures regarding the formal registering of applications for type approval with the Issuing Authority, notifying the Issuing Authority of non conformances with regard to instruments under test, lack of requirements for obtaining authority to make adjustments and lack of requirements for checking data transfers and securing of data.

WD CPR - 05: Conclusions of the PA (cont.)

(f) Once the non conformances have been addressed, it is concluded that the ISO/IEC 17025 laboratories will be suitable as testing laboratories for providing test results according to OIML R 76 to the PTB as Issuing Authority for evaluation of conformity under the DoMC for OIML R 76.

WD CPR - 05: Conclusions of the PA (cont.)

(g) In both cases the MTLs play an important role also for ensuring conformity to type of the serial production instruments, because both manufacturers use their R76 MTLs not only for type tests but also for substantial statistical tests that ensure quick recognition and correction of possible deviations outside the maximum permissible errors.

Use of Test Results of MTLs under the OIML MAA

1. Background and Motivation

Roman Schwartz

2. Report about the Peer Assessments at Sartorius DE and Mettler Toledo CH (20 - 24 April 2009)

- Experiences, Major Results and Conclusions -

Jaco Marneweck

3. WD CPR-05 and Proposals to the CPR

Roman Schwartz

- Discussion -

WD CPR - 05 / Ch. 4: Proposals to CPR

After discussion of the experiences, results and conclusions of the two peer assessments the peer assessment team - in view of Resolution No 20 of the 43rd CIML meeting - agreed to put forward the following proposals to the CPR meeting in June 2009.

WD CPR - 05: Proposals to the CPR (cont.)

(a) Requirements for MTLs:

There should be no different requirements defined for MTLs; MTLs should be treated the same as any other ISO/IEC 17025 testing laboratory (references: ISO/IEC 17025:2005, OIML D30:2008).

But for MTLs emphasis should be put on:

- clear (transparent) procedures for authorised and controlled testing (documented in the QMS (ISO/IEC 17025) of the MTL (reference: OIML D30: G.4.2.2-1, G.4.4.1-1, G.4.9.1-1, G.5.4.1-1) and the QMS (ISO/IEC 65) of the Issuing Authority (reference: OIML D29: G.4.3-2 and G.4.4-6)

WD CPR - 05: Proposals to the CPR (cont.)

...

- the MTL is embedded in a certified QMS (ISO 9001:2000 (or later: 2008)) of the mother company that ensures - by appropriate means - the independence, integrity etc. of the MTLs personell (reference: D30: G.4.1.4-1 and ISO/IEC 17025, No 4.1.4, in particular Note 2);

the MTL shall also be used for ensuring conformity to type of the serial production instruments by appropriate QM procedures.

WD CPR - 05: Proposals to the CPR (cont.)

(b) Procedures for assessing MTLs:

There should be no different procedures for assessing MTLs; MTLs should be treated the same as any other ISO/IEC 17025 testing laboratory (references: OIML B10-1 and B10-2).

But for MTLs emphasis should be put on:

- B10-2: 4.2.1 (organisation)
- B10-2: 4.2.2 (quality system)
- B10-2: 4.3 (technical requirements)

WD CPR - 05: Proposals to the CPR (cont.)

(c) Treatment of MTLs in a DoMC:

There should be the same treatment of MTLs in a DoMC, i.e. if an Issuing Authority takes responsibility for a MTL, and the assessment of the MTL according to the CPR rules is positive, the MTL will be listed in the DoMC as any other Testing Laboratory associated with an Issuing Authority (see e.g. Table 3 in the DoMC R76).

Different Issuing Authorities should be allowed to designate the same MTL.

Example: MT-CH has been designated by PTB already, but is intended to be designated by METAS, too.

WD CPR - 05: Proposals to the CPR (cont.)

(d) Changes / Additions to B10-1, B10-2 and D30:

The following changes / additions to B10-1, B10-2 and D30 should be proposed by the CPR* to TC3/SC5 in order to include MTLs in the scope of the MAA.

**Note:*

The CPR has not to decide, but TC3/SC5 will certainly observe any CPR proposal concerning the issue of MTLs.

WD CPR - 05: Proposals to the CPR (cont.)

(1) Changes / Additions to B10-1:2004:

> **No changes / additions necessary concerning MTLs.**

WD CPR - 05: Proposals to the CPR (cont.)

(2) Changes / Additions to the Amendment (2006) to B10-1:

> No changes / additions necessary concerning MTLs.

WD CPR - 05: Proposals to the CPR (cont.)

(3) Changes / Additions to B10-2:2004:

B10-2 must be generally

- updated according to ISO 17025:2005,
- adapted to D30 (2008) and
- reviewed for relevance and clarity of statements to be checked.

WD CPR - 05: Proposals to the CPR (cont.)

(4) Changes / Additions to D30:2008:

D30 should be amended as follows with regard to MTLs:

(a) Add a paragraph (or note) to G.4.1.4-1:

A MTL will be regarded as a third-party laboratory under the MAA, if it is part of a certified quality management system according to ISO 9001:2000 (later: 2008) of the mother company that ensures – by appropriate organisational provisions and procedures – impartiality, independence and integrity of its personnel, and conformity to type of the serial production instruments.

WD CPR - 05: Proposals to the CPR (cont.)

(4) Changes / Additions to D30:2008 (cont.):

(b) Trace issues concerning the interrelationship between the Issuing Authority and a MTL regarding authorisation and control of units under test (G.4.2.2-1, G.4.4.1-1, G.4.9.1-1, G.5.4.1-1).

(c) Emphasize training / involvement of MTLs personnel in international work in the field of legal metrology (especially in OIML) (G.5.2.1-1).

Note: It is the special responsibility of the Issuing Authority and the CIML member to involve the MTL in the international work of OIML, including information about ongoing revisions, comments etc.

WD CPR - 05: Proposals to the CPR (cont.)

(4) Changes / Additions to D30:2008 (cont.):

(d) Emphasize the maintenance of technical records at the MTL (G.4.13.1.2-1)

(e) The MTL to participate in bilateral intercomparison(s) with the Issuing Authorities Testing Laboratory as prerequisite for participation in the MAA (BIML to consider intercomparisons in the near future in line with G.5.9.1-1)

WD CPR - 05: Proposals to the CPR (cont.)

(4) Changes / Additions to D30:2008 (cont.):

(f) In both cases, accreditation or peer assessment (PA) of the MTL, the assessment team shall comprise a validated technical and metrological expert and a validated lead assessor (within the MTLs accreditation cycle or at least once every four years).

WD CPR - 05: Proposals to the CPR (cont.)

(4) Changes / Additions to D30:2008 (cont.):

(g) In case of PA the re-assessments of the MTL are performed at the same frequency as for accredited MTLs (e.g. 18 months).

Note: In the special case that one MTL supplies test reports to more than one Issuing Authority, the CPR should decide who would contact / assess the MTL.

Conclusion

- **With the proposed amendments of D30 - the revision of B10-2 is necessary anyway - the issue of MTLs will be fully addressed** (no "extra paper" necessary for MTLs)
- The MAA will be in line with the **OIML-ILAC-IAF MoU (Oct. 2007)**
- **Everything important will be included in the scope of the MAA** so that any discussion about "Basic Certificates for issues outside the scope of the MAA" will be obsolete
- The door will be wide open for a **really successful MAA** that offers **added value to our customers** and is really adequate for the global market
- **We shall support** those manufacturers who take **Conformity To Type (CTT)** seriously, and shall **make a big step towards a better CTT**
- **Time frame:** Next TC3/SC5: spring 2010/ 44. CIML: Sept. 2010/ Revision of rel. documents/ **Start with revised docs and rev. MAA/ DoMC: 2011**

Conclusion (cont.)

Finally, how could the revised R76 DoMC look like?

3. OIML Issuing Authorities and their Testing Laboratories

State	Issuing Authority	Testing Laboratory
Australia	NMI, National Measurement Institute of Australia	NMI, National Measurement Institute of Australia
China	AQSIQ, General Administration of Quality Supervision, Inspection and Quarantine	NIM, National Institute of Metrology
France	LNE, Laboratoire National de Métrologie et d'Essais	LNE, Laboratoire National de Métrologie et d'Essais
Japan	NMIJ/AIST, National Metrology Institute of Japan	NMIJ/AIST, National Metrology Institute of Japan
Korea (R.)	KATS, Korean Agency for Technology and Standards	MPI, Korea Machinery-Meter and Petrochemical Testing & Research Institute
New Zealand	MCA/MAPSS, Ministry of Consumer Affairs Measurement and Product Safety Service	MCA/MAPSS, Ministry of Consumer Affairs Measurement and Product Safety Service
Slovakia	SLM, Slovak Legal Metrology (Banská Bystrica)	1) SLM, Slovak Legal Metrology 2) EVPŮ, Elektrotechnický výskumný a projektový ústav
Sweden	SP Technical Research Institute of Sweden	SP Technical Research Institute of Sweden
United Kingdom	NWML, National Weights and Measures Laboratory	NWML, National Weights and Measures Laboratory
Netherlands	NMI Certin B.V.	NMI Certin B.V.
Switzerland	Federal Office of Metrology METAS	Federal Office of Metrology METAS
Germany	Physikalisch-Technische Bundesanstalt	1) PTB, Physikalisch-Technische B. 2) Sartorius AG, Goettingen 3) Mettler Toledo, Switzerland 4)

PTB application:
 ← Step 1
 ← Step 2
 ← Step 3

4th CPR meeting, 17-19 June 2009

**Use of Test Results from
Manufacturers' ISO/IEC 17025 Test Laboratories (MTLs)
within the Scope of the
OIML Mutual Acceptance Arrangement (MAA)**

**Thank you for your attention!
It's time for discussions!**

ANNEX V

Revised maintenance scheme of DoMCs

