BIML 09 No 395/RG 7 August 2009

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 apologizes 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.

R. Gaucher also informed the participants that Mr. Kallgren, who was the representative of Sweden in the R 76 CPR, has left SP due to his retirement. She indicated that she had contacted the Swedish CIML Member to appoint a new Swedish representative in the R 76 CPR and a new contact for the OIML Issuing Authority and Issuing Participant (SP).

R. Gaucher thanked the participants for having accepted a number of observers:

- Mr. Gilles Vinet from Measurement Canada;
- Dr. Oliver Mack from the PTB who should become the German representative in the R 60 CPR after the acceptance of the PTB as an Issuing Participant. Mrs. Gaucher reminded the participants that the PTB's application would be discussed at the R 60/R 76 CPR meeting to be held on 19 June;
- Mr. Ferreira, who is going to replace Mr. Marneweck in the R 60/R 76 CPR as representative of South Africa;
- Mr. Couvreur from METAS who applied to become a technical and metrological expert for OIML R 76 and whose candidacy would be examined at the R 60/R 76 CPR meeting on 19 June.

The list of participants is given in Annex I to the present minutes.

Dr. Philippe Richard welcomed the participants and made a presentation of METAS and its various departments (calibration, certification, type approval, etc.). He also highlighted the fact that the accreditation body SAS is now a fully separate entity, even though it is still located on the premises.

METAS depends on the Department of Justice and Police (Ministry) in Switzerland. It has 48 verification offices and 76 mandated verification laboratories involved in subsequent verification, market surveillance and control of prepackages.

Participants had the opportunity to visit the various laboratories located on the METAS site in Bern-Wabern.

R. Gaucher explained the reasons for holding such a combined R 49/R 60/R 76 CPR meeting: the aim was to discuss general issues on the implementation of the MAA and on the operating rules of the DoMCs, in the light of the experience gained with the first three DoMCs and the difficulties encountered in particular with their maintenance.

She indicated that other issues had been added to the agenda due to the resolutions adopted at the last CIML Meeting and to the ongoing work of OIML TC 3/SC 5 on the revision of OIML B 3 and OIML B 10-1.

A round table was also organized to allow each Participant to introduce him or herself.

4 Approval of the agenda

The Agenda revision 3, ref. BIML 09 No. 174/RG dated 8 June 2009, was adopted.

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

R. Gaucher began by informing participants of the new wording related to the OIML Certificate System based on OIML B 3, which is "OIML *Basic* Certificate System" as agreed by OIML TC 3/SC 5. Cock Oosterman indicated that such terminology should also be used in the title of the Certificates since currently Certificates issued under the MAA and those issued outside the MAA were distinguished by their logo only. R. Gaucher indicated that the TC 3/SC 5 Secretariat will take into account this suggestion when drawing up the 2CD for the revision of OIML B 3.
Afterwards, R. Gaucher gave a short presentation based on the working document WD R 49/R 60/R 76 CPR-01:

- To present the four Resolutions approved at the 43rd CIML Meeting and related to the implementation of the OIML Basic Certificate system and the MAA;
- To present the changes in the inclusion procedure of an OIML Recommendation in the OIML Basic Certificate System;
- To confirm that for a given category, the MAA and the OIML Basic Certificate System would stay in parallel until a CIML decision to stop the latest one;
- To reiterate that CPR Members were invited to provide inputs to OIML TC 3/SC 5 to take into account test results from manufacturers within the MAA.

The presentation is given in Annex II to the present minutes.

Paul Dixon raised the question about the registration fees for a revised Certificate which could be less than for an initial Certificate.

R. Gaucher indicated that these fees are linked to the work of the BIML (review of the Certificate before registration, registration in the OIML database, issuing of the invoice, etc.) and the work is identical whether it is an initial or a revised Certificate.

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

R. Gaucher reminded participants that the minutes of the OIML TC 3/SC 5 meeting held in May 2008 in Paris were available to everybody on the OIML TC 3/SC 5 pages of the OIML web site:
http://workgroups.oiml.org/tcsc/tc3sc5/meeting-may-2008

She indicated that three issues were currently under the responsibility of TC 3/SC 5:

- The revision of OIML B 3 related to the OIML Basic Certificate System;
- The revision of OIML B 10-1 related to the MAA which should become an additional Publication to OIML B 3 since the MAA is considered as an additional tool to the OIML Basic Certificate System;
- Project p2 related to uncertainties in legal metrology.

The presentation is given in Annex III to the present minutes.

R. Gaucher pointed out in particular the following issues:

- Revision of the terminology to be harmonized in OIML B 3 and OIML B 10;
- Both accreditation and peer assessments will be maintained as means to demonstrate competence on the basis of ISO/IEC 17025 and OIML D 30;
- Revision of the layout of the Certificates to highlight the subject of the Certificate (revision, transfer, etc.) and the minimum characteristics to be included to describe the type of measuring instrument. The definition of such minimum characteristics could be under the responsibility of the relevant TC/SC when drawing up the OIML Recommendation;
- Immediate previous edition of a revised OIML Recommendation maintained in the OIML Basic Certificate System together with the new edition;
- No limit of validity of OIML Certificates (Basic and MAA);
- OIML B 10-2 to be withdrawn and replaced by a Format for an internal report to be submitted to CPR Members (see item 8 below) and a format of the audit report to be used by National Accreditation Bodies and for peer assessments.

Nathalie Dupuis-Desormeaux requested information about the voting rules in the CPR in the event that there are several Participants in a DoMC for a same country.

R. Gaucher replied that proposals would be included in the 1CD for the revision of OIML B 10-1.
Dr. Charles Ehrlich emphasized the deadline fixed at 15 September 2009 to comment on the 1CD circulated on uncertainties.

7 Type approval test results provided by manufacturers of measuring instruments

7.1 Discussions

R. Gaucher reminded the participants of the scope of this issue. She indicated that this issue was related to tests performed by the manufacturer itself in its internal laboratory. Manufacturers' Testing Laboratories (MTLs) referred to in these discussions conform to ISO/IEC 17025.

She cautioned that tests performed by the Issuing Participant at the manufacturer's premises were not covered by this issue and were already included in the MAA. In such a case the Issuing Participant is responsible for the tests and should have appropriate procedures, in particular related to the validation of the testing facilities to be used when those do not belong to it.

She also pointed out the fact that this issue is related to tests performed by the manufacturer after it has sent its application to the Issuing Participant.

The issue of using test results from MTLs within the scope of the MAA was discussed on the basis of WD R 49/R 60/R 76 CPR-05 and a presentation given by R. Schwartz which is available in Annex IV to these minutes.

R. Schwartz began by recapitulating the background and motivation for including MTLs in the scope of the MAA by reminding CPR Members of Resolution 2008/04 of the last TC 3/SC 5 meeting (May 2008) and Resolution No 20 of the 43rd CIML Meeting (October 2008). In Resolution 2008/04 the proponents of the acceptance of MTL test results were requested to provide an explanation of the conditions, and an example.

In Resolution 20, the CIML confirmed its support for 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 could be reached on the conditions to be applicable to MTLs. R. Schwartz also explained why the issue of MTLs is important for the success of the MAA by providing four reasons:

a) The implementation of the OIML-ILAC-IAF MoU (signed in October 2007);
b) An analysis of the OIML Certificate Data Base (since 1991);
c) Lingering misunderstandings and prejudices to be resolved; and finally
d) The relationship between the issue of MTLs and the issue of Conformity to Type (CTT).

R. Schwartz and J. Marneweck (South Africa) went on to present the program, experiences and conclusions of two voluntary peer assessments organized by the PTB at the MTLs of Mettler Toledo (Switzerland) and Sartorius (Germany) based on the above-mentioned resolutions of TC 3/SC 5 and the CIML.

The main conclusion of the lead assessor (Mr. Brian Beard, South Africa) in both peer assessment reports - which were made available to CPR Members - can be summarized as follows: "No evidence was found to indicate that the activities of either MTL or their relation to the manufacturing divisions of the parent companies will compromise their independence, judgment, impartiality or operational integrity."

Lastly, R. Schwartz presented several proposals of the peer assessment team as regards the conditions and criteria to be applicable to MTLs under the MAA, in view of Resolution No 20 of the 43rd CIML Meeting.

In the following two aspects were mainly discussed:

- The principle to take into account test results from MTLs of tests performed by manufacturers in order to issue an OIML MAA Evaluation Report and an OIML MAA Certificate;

- The criteria to be defined to ensure in particular impartiality, independence of judgment, absence of conflict of interest and fair access for all manufacturers (transparency, equitability).

Even if the discussions started on the basis of the experience presented for Mettler Toledo and Sartorius testing laboratories, participants agreed to discuss the matter on a general basis to define general criteria. J. Marneweck and R. Schwartz emphasized that this had exactly been the goal of the two peer assessments.

C. Lagauterie indicated that impartiality was already addressed in ISO/IEC 17025 and OIML D 30. She felt that independence was the critical issue as it was foreseen by WELMEC with the application of module B (type examination) of the European Directive. She mentioned that the independence criteria will be emphasized in the revision of the New Approach.

In particular, C. Lagauterie indicated that the identification of the instrument to be tested shall be covered between the Issuing Participant and the testing laboratory and that it is more tricky when the laboratory is that of the manufacturer which applies for type approval (e.g. the instrument may be stamped and sealed by the Issuing Participant after its examination and before being tested). She also emphasized the need to guarantee the integrity of the instrument during testing and the strict application of the testing procedures (no deviation without authorization and control of the Issuing Participant).

J. Truex indicated that in his opinion the management of the company did not really interfere with the evaluation but that relations with the market and the marketing department are more crucial.

R. Schwartz replied that internal quality procedures may assist in demonstrating that there is no interference between the relevant departments of the company.

C. Ehrlich raised three points to be addressed when revising documents OIML B 3 and OIML B 10:

a) The development of an appropriate process/ procedure for auditing an MTL to confidently assess their impartiality from the parent company;
b) The establishment of clear and acceptable criteria that an MTL must satisfy in order that its test data would be acceptable under the MAA;
c) The definition of a minimum frequency of unannounced audit of an MTL.

C. Lagauterie indicated that, in addition to a), it would be important to also assess the links between the MTL and the respective Issuing Authority.

P. van Breugel added that independence might and could be organized within a company by effective quality management measures.

P. Dixon confirmed this by mentioning that in the case of Avery Berkel's test laboratory for load cells (capacities > 2000 kg) the issue of independence could easily be solved by UKAS accreditation.

J. Barton pointed out that management systems (such as those of Mettler Toledo and Sartorius) were available in all companies and would allow such identification of interferences between departments.

N. Dupuis-Désormeaux indicated that the MAA should be equitable and transparent. Introducing tests performed by manufacturers could lead to a loss of trust in Certificates. She added that the MAA currently allowed the manufacturers' testing facilities to be used as soon as the tests are performed by the Issuing Participant (with or without the manufacturer's personnel).

P. Dixon indicated that witnessing tests is not sufficient.

R. Gaucher reminded participants of her preliminary comments and confirmed that witnessing tests alone is not sufficient, but may be an additional tool to guarantee confidence.

G. Couvreur also reminded participants that at the end of the process, the Issuing Participant is responsible in any case for evaluating the test results before drawing up the Evaluation report.

G. Vinet indicated that the key issue was independence; competence is not a real problem. In his opinion, a cost analysis should also be taken into account depending on the number of tests performed by manufacturers. Sometimes, it could be less expensive for Issuing Participants to carry out the tests at the manufacturer's premises.

G. Harvey mentioned that a conflict of interest was more important than independence only.

P. Dixon pointed out that there was a public ISO Document which expressed how to address conflicts of interest. He also mentioned that independence of the MTL should not be confused with independence of the Issuing Participant.

Finally, the combined R 49/R 60/R 76 CPR agreed to give further consideration to the following draft proposals.

7.2 **CPR proposals**

- Requirements shall be the same for any testing laboratory (third-party and manufacturer's testing laboratory);
- Requirements for the evaluation of testing laboratories shall be based on ISO/IEC 17025 and OIML D 30;
- Revision of OIML D 30 shall address interpretation and/or requirements to prevent any conflict of interest and to guarantee independence and impartiality of testing laboratories (ISO/IEC 17025 § 4.1.4);
- Criteria to be added into OIML D 30:
    - *Guidance to 4.1.4 to be added and/or clarified*
      A manufacturer's testing laboratory (MTL) is considered as part of an organization performing activities other than testing. Consequently a potential conflict of interest exists.
      Procedures to avoid any conflict of interest, any undue commercial, financial and other pressures which might influence the technical conclusions of testing laboratories shall be defined in the quality management system of the manufacturer.
      In the case of MTLs, these procedures shall define interactions between the MTL and the other departments of the company. In particular, the following procedures are mandatory:
        - Top management commitment (as defined in ISO 9001 § 5.1);
        - …. (to be completed)

      An ISO 9001 certification of the manufacturer's quality management system (by an accredited Certification Body) is considered as one feasible (but not the only one) way for a manufacturer to fulfill these requirements.
    - *Guidance to 5.4.1 to be added*
      The testing laboratory shall have procedures which define its operation with the Issuing Participant (OIML D 30 G. 5.4.1 and clarification in OIML B 3 to be added in particular concerning identification and integrity of the instrument to be tested).
    - *Guidance to 5.9.1 to be modified*
      Each testing laboratory (MTLs and third-party testing laboratories) shall participate in intercomparisons with at least one other testing laboratory which is registered in the DoMC (periodicity to be defined).

CPR Members are kindly invited to provide the CPR Secretariat (Régine Gaucher, BIML) with additional comments and suggestions to complete the above-indicated inputs at the latest by 30 November 2009.

Afterwards, a final proposal will be drawn up and submitted to OIML TC 3/SC 5 with a view to it being discussed at the next meeting of TC 3/SC 5 (possibly spring 2010).

8 Maintenance and renewal of DoMCs

8.1 Discussions

R. Gaucher presented the difficulties encountered when conducting the intermediate documentary assessments of Issuing Participants in the R 60 and R 76 DoMCs. The presentation was made on the basis of WD R 49/R 60/R 76 CPR-02 and the slides which are given in Annex V to the present minutes.

The main difficulties encountered were:

- The inconsistency of information submitted to CPR Members, in particular depending on whether the testing laboratory is accredited or peer-assessed;
- Different accreditation cycles in the various countries even if they all fulfil ILAC Guidance;
- For testing laboratories accredited for a broad scope, according to the ILAC Guidance, the whole scope shall be assessed at least once within an accreditation cycle (e.g. the legal metrology scope may be assessed only once in five years).

She also presented information on the assessments conducted within the CIPM MRA which also uses accreditation, in particular to assess quality management systems.

8.2 Proposals

To increase consistency in the reports and information to be reviewed by CPR Members, CPR Members suggested that the maintenance process of a DoMC should include:

- The review of an internal report once a year submitted by the Issuing Participant. This report should highlight in particular:
    - Results of comparisons
    - Changes in personnel, structures and organization
    - Results of management reviews
    - Results of internal audits
    - Complaints received

  R. Gaucher will contact SIM in order to obtain a copy of the annual report they request within the maintenance process of the CIPM MRA.

- A review of the accreditation assessment and peer assessment reports of Issuing Participants every five years. Issuing Participants whose testing laboratories are peer assessed will be responsible for organizing their peer assessments every five years under the conditions of OIML B 10-1 and of the MoU between ILAC and the OIML, in particular for the designation of the assessment team. Issuing Participants whose testing laboratories are accredited will be responsible for requiring their National Accreditation Body to include an expert from the ILAC/IAF/OIML List as soon as the relevant scope of the DoMC is included in the assessment. Considering a five year renewal period and the ILAC Guidance, all the testing laboratories will be able to submit at least one accreditation assessment report which includes the relevant scope of the DoMC.

CPR Members suggested revising the maintenance process on the occasion of the revision of OIML B 10-1. Consequently, the intermediate documentary assessment of Issuing Participant in the R 49 DoMC and the renewal of participations in the R 60 and R 76 DoMCs will be conducted according to the existing rules (defined in OIML MAA 01).

The revised maintenance scheme is shown in Annex V.

In addition, CPR Members suggested revising the voting rules within CPRs in order that the processes should not be delayed by a lack of replies. The same difficulty is encountered in OIML TCs/SCs and in CIML postal approval of OIML Recommendations. The Directives for the OIML Technical Work are under revision and CPR Members suggested aligning their future rules on those which will be decided on for the revision of the Directives (e.g. no reply is considered as abstention and abstention is not taken into account in the decision process, defining a maximum of "no" votes).

9 Revision of the registration format of the DoMCs

This item was discussed on the basis of WD R 49/R 60/R 76 CPR-03.

CPR Members agreed to revise the format for the registration of a DoMC, in particular to clarify the following issues:

- Date of registration of each Participant (Issuing and Utilizing);
- Date of changes in participation status;
- Clarification of testing capabilities (in particular to harmonize the presentation of the testing capabilities across the various testing laboratories (e.g. presentation of physical test capabilities or "virtual" test capabilities when using the modular approach) and to highlight the fact that the use of external testing facilities may lead to higher capabilities).

10 Conditions under which Issuing Participants may still issue OIML Basic Certificates

This item was discussed on the basis of WD R 49/R 60/R 76 CPR-04. The objective was to clarify the meaning of the following part of Resolution no. 20 which was approved at the 43rd CIML Meeting:

"…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…"

CPR Members concluded that the following tests are considered to be outside the scope of the DoMCs and could oblige an Issuing Participant to issue an OIML Basic Certificate instead of an OIML MAA Certificate:

- Tests, the results of which are issued by manufacturers;
- Tests performed on the basis of the relevant OIML Recommendation but outside the scope of the testing capabilities of the Issuing Participants as defined in the DoMC (e.g. NMO, United Kingdom, is registered in the R 49 DoMC for mechanical water meters only. NMO may issue Basic Certificates for electronic meters);
- Tests, the results of which are taken into account from a Basic Evaluation Report (e.g. certification of a new type which is derived from a previously certified one (change in the software) and the Issuing Participant does not repeat all the tests).

This clarification will be submitted for approval at the 44th CIML Meeting, in particular for transparency and information of Issuing Authorities which do not participate in the DoMCs.

Note (post-minutes): Since the CIML already adopted the Resolution at its 43rd Meeting, the BIML Director recommended issuing a Circular to clarify the situation: please refer to Circular 09/374 dated 2009.07.23.

11 Information concerning cooperation between the OIML and ILAC on conformity assessment

R. Gaucher presented the draft joint ILAC/OIML Working Program which was revised for 2009 and 2010 further to the meeting held in March 2009 between the two Organizations.

She indicated that she had just received the agreement on the draft from ILAC and that consequently, it should be possible to publish it shortly.

R. Schwartz commented that the reference at the beginning of the document should be the MoU between ILAC, IAF and the OIML signed in 2007 since it replaced the previous MoU signed between ILAC and the OIML in 2006.

12 Additional issues
&
13 Other issues

C. Oosterman pointed out the fact that load cells tested on the basis of OIML R 60 would not automatically be able to be used in a non-automatic weighing instrument to be certified on the basis of OIML R 76.

R. Gaucher indicated that this issue would be addressed on 19 June at the R 60/R 76 CPR meeting.

R. Gaucher informed CPR Members that after the CPR meetings, a new DoMC on the basis of R 51 would be launched.

In addition, at the request of manufacturers, she mentioned that a proposal would be submitted for approval by the CIML at its 44th meeting to launch a DoMC on the basis of R 117:1995 and R 118:1995 for fuel dispensers with additional requirements from OIML R 117-1:2007.

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

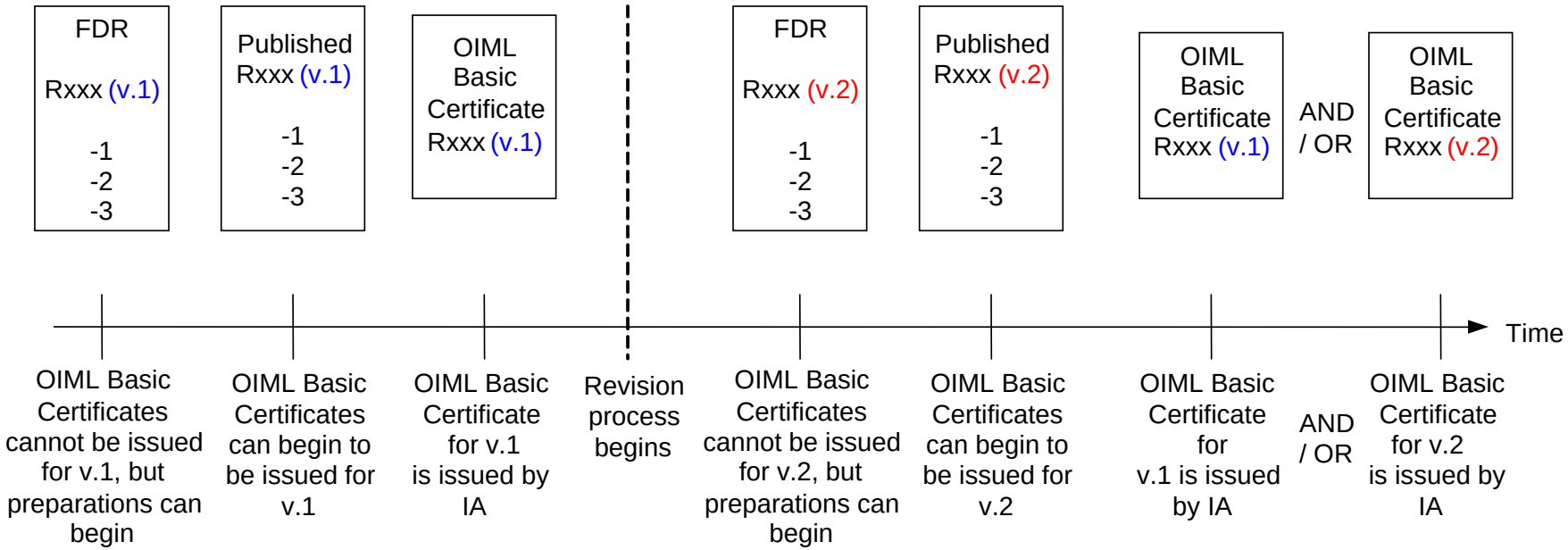
CIML Resolution no. 18

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.

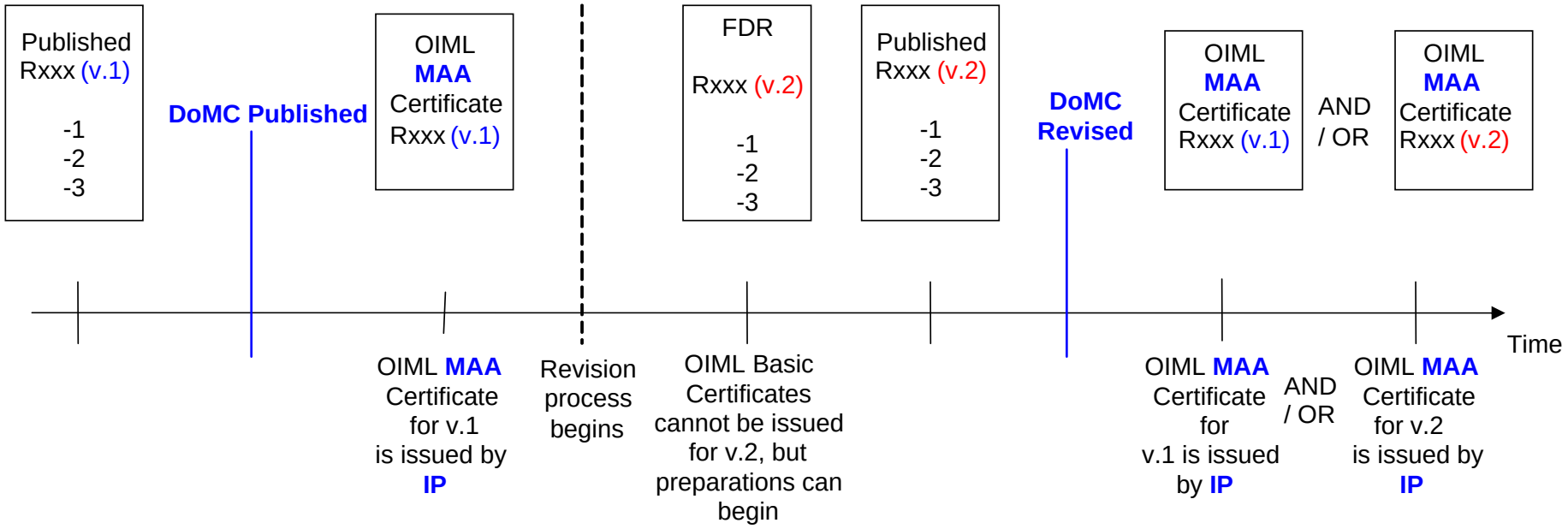
The official date from which an OIML Basic Certificate can be issued is the date on which the OIML Publication appears on the OIML web site. This date shall be recorded in the table of Publications available on the OIML web site.

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

CIML Resolution no. 18 & 19



CIML Resolution no. 18 & 19



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**

CIML Resolution no. 19

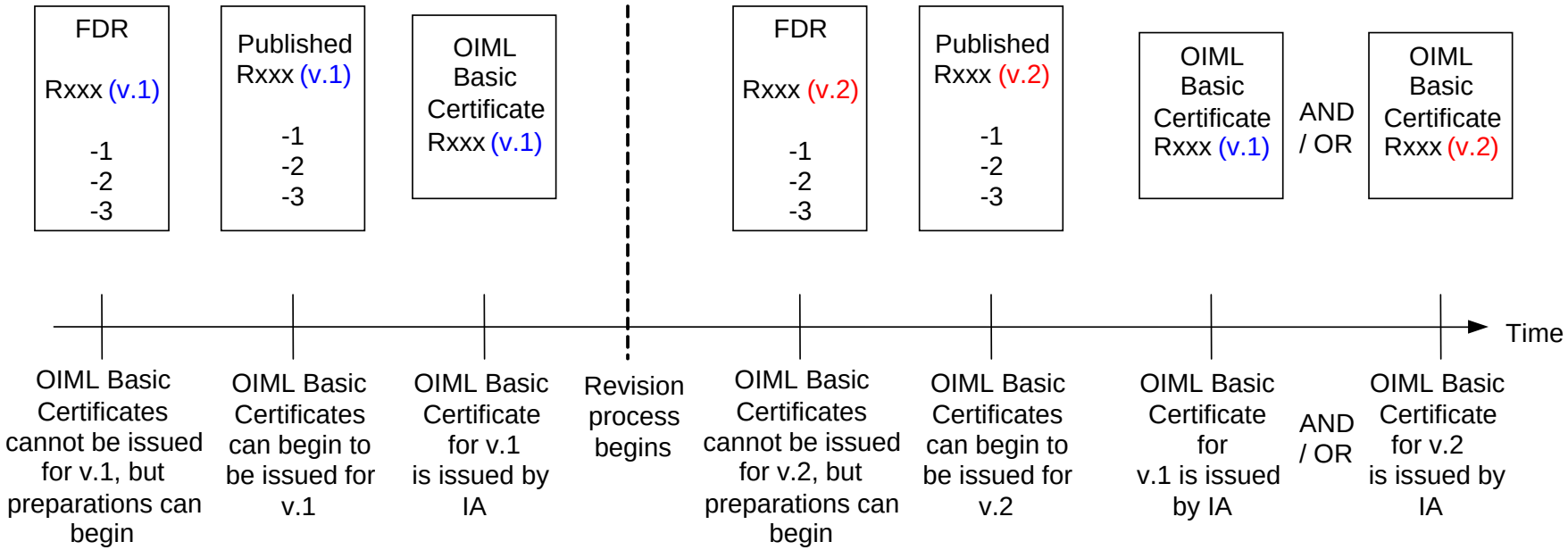
As soon as an OIML Recommendation, including the Test Report Format is published, the relevant OIML Recommendation is automatically included in the OIML Basic Certificate System. The Bureau will publish the appropriate information on the web site

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

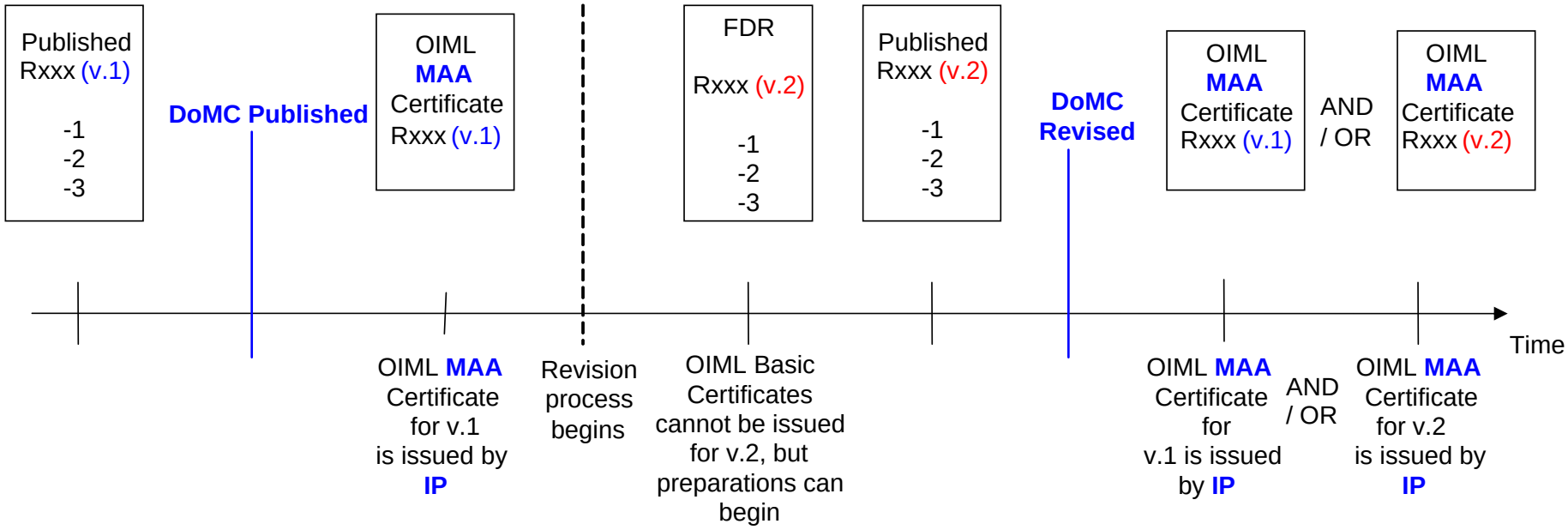
A comparison document between the two versions, drawn up by the appropriate TC/SC Secretariat, is no longer required

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. 18 & 19



CIML Resolution no. 18 & 19



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

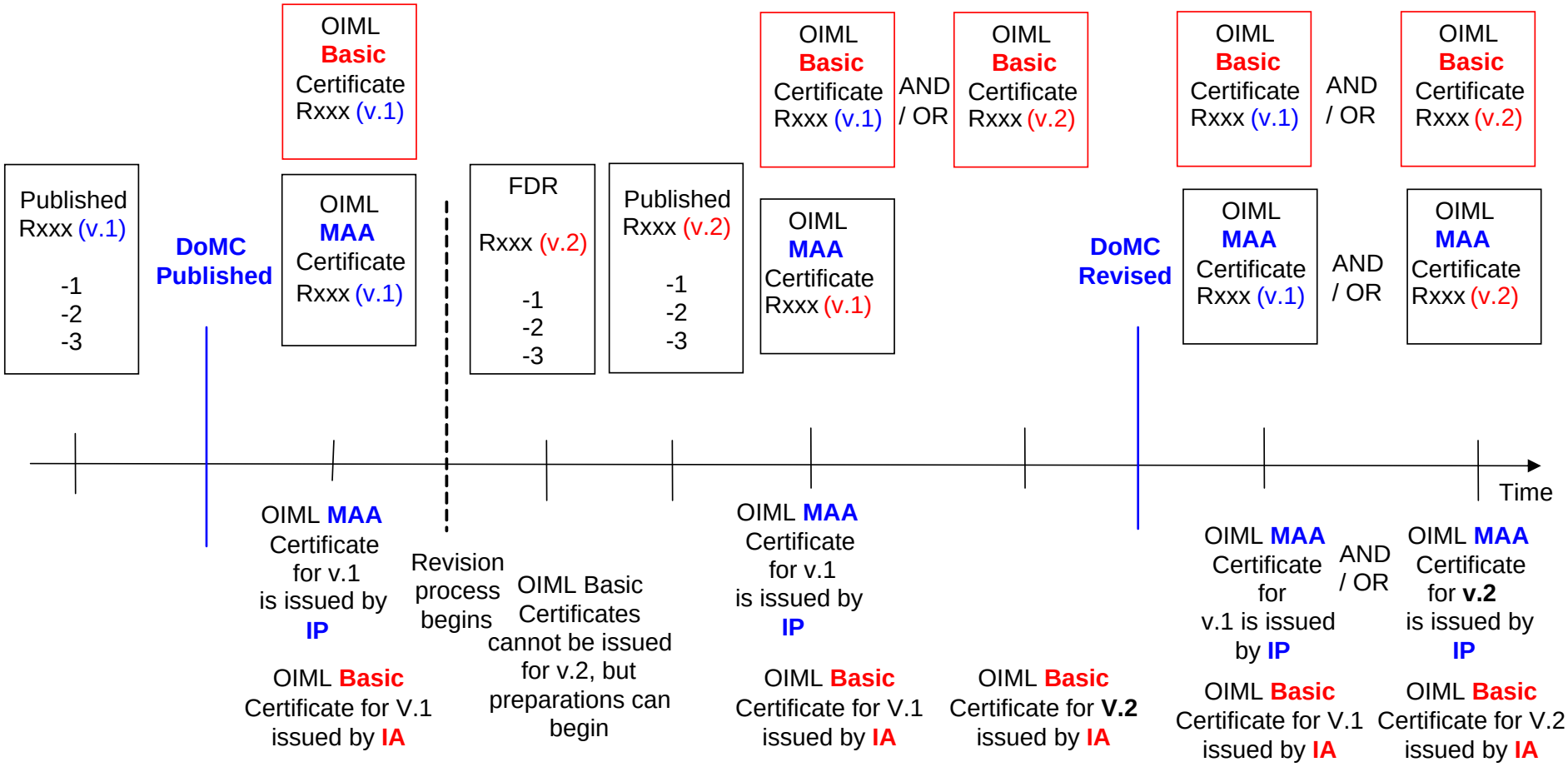
The OIML Basic Certificate System and the OIML MAA are maintained in parallel for categories under the MAA until the Committee decides to stop the implementation of the OIML Basic Certificate System. The proposal to stop the OIML Basic Certificate System for a particular category shall be examined, as 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.

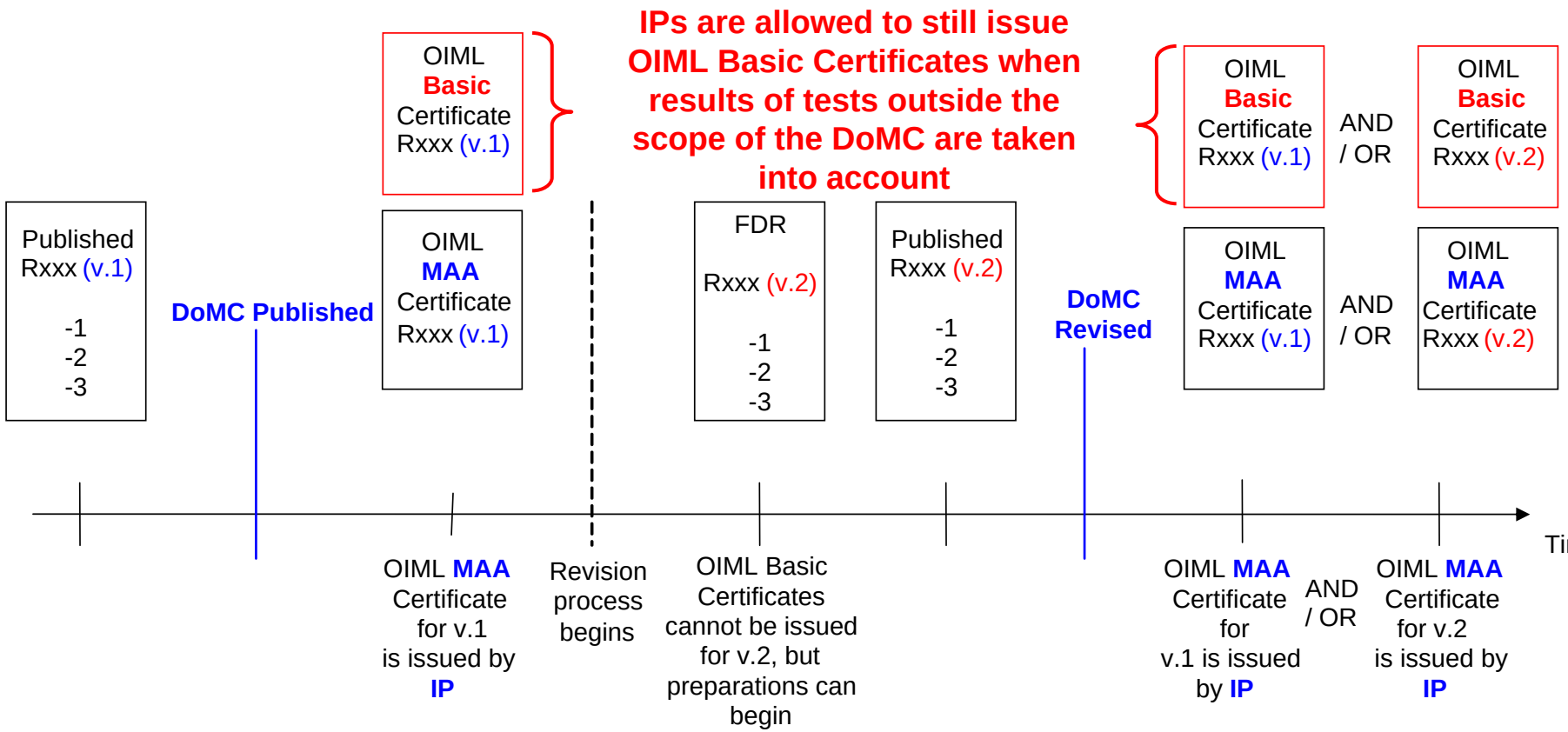
CIML Resolution no. 20

Application before the OIML Basic Certificate System is stopped



CIML Resolution no. 20

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

CIML Resolution no. 21

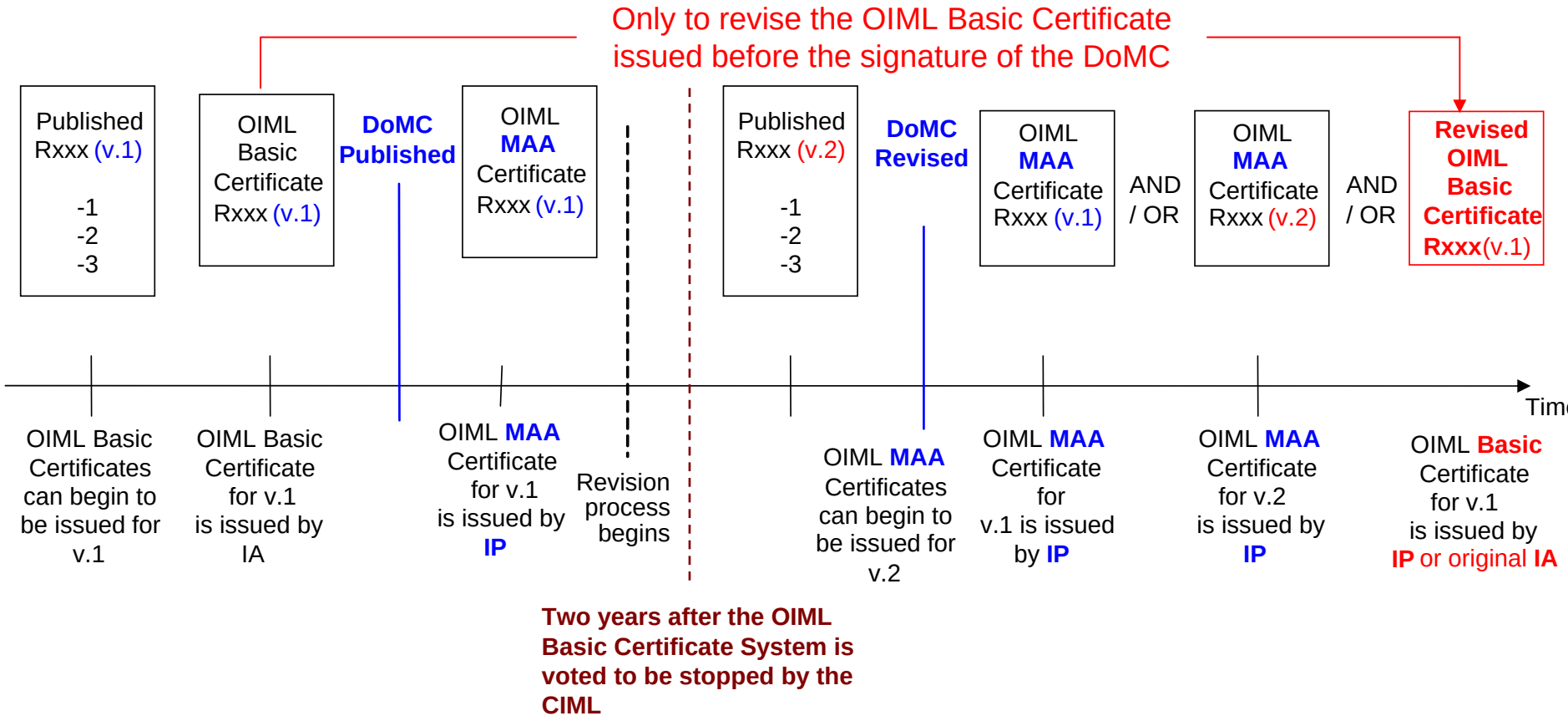
After the OIML Basic Certificate System for a particular category of instrument has been stopped, when an applicant requests a revision (see the Note below) of an OIML Basic Certificate based on the same version of the OIML Recommendation, which has been subsequently covered by the MAA, the revised OIML 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

CIML Resolution no. 21

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

Revision of OIML B 3

- 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

Revision of OIML B 10

- **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**

Revision of OIML B 10

- **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**

Revision of OIML B 10

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 tome 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

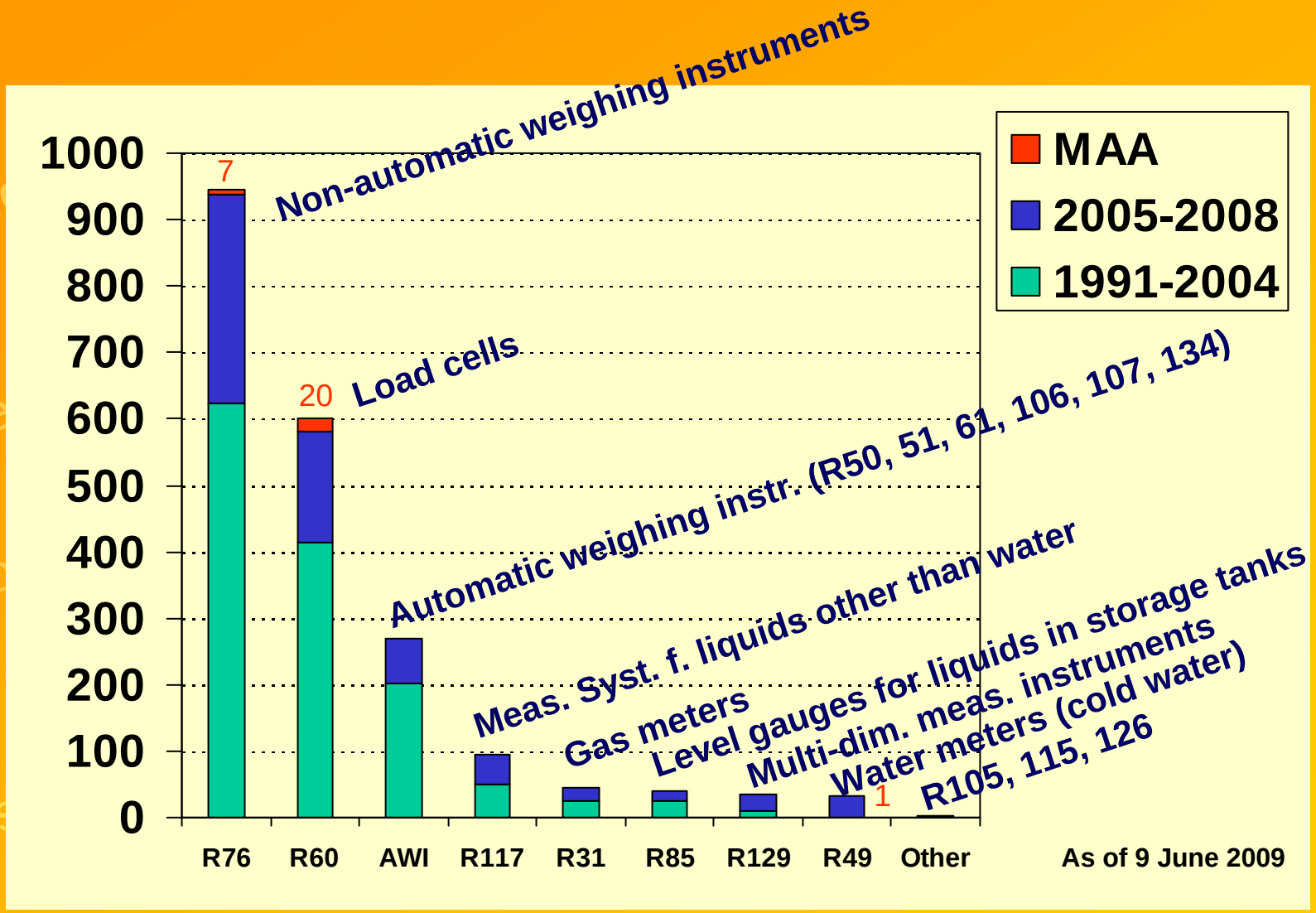
> Basic Certificates 2005 - 2009

> MAA Certificates 2006 - 2009

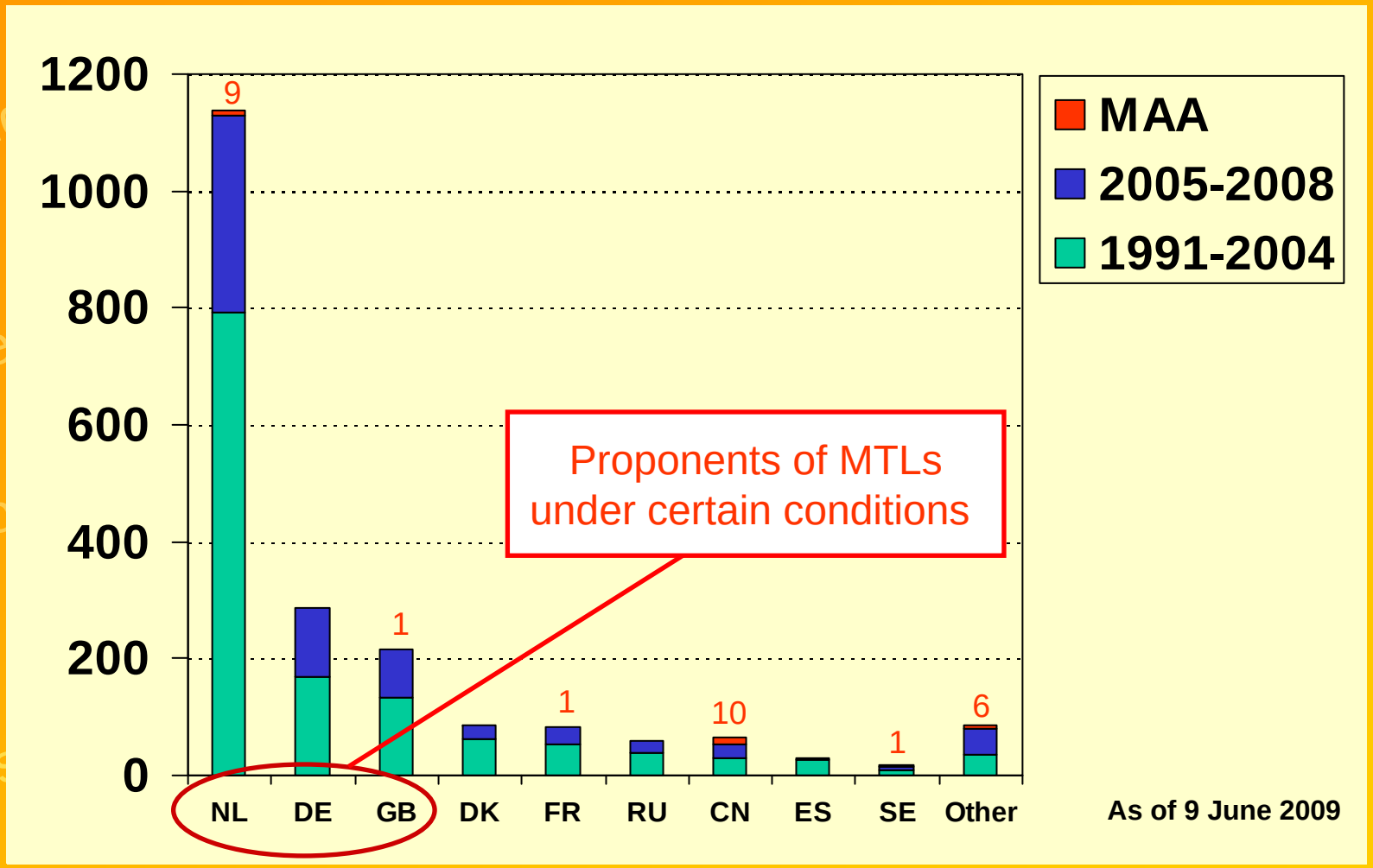
Analysis of OIML Certificate Data Base

- **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

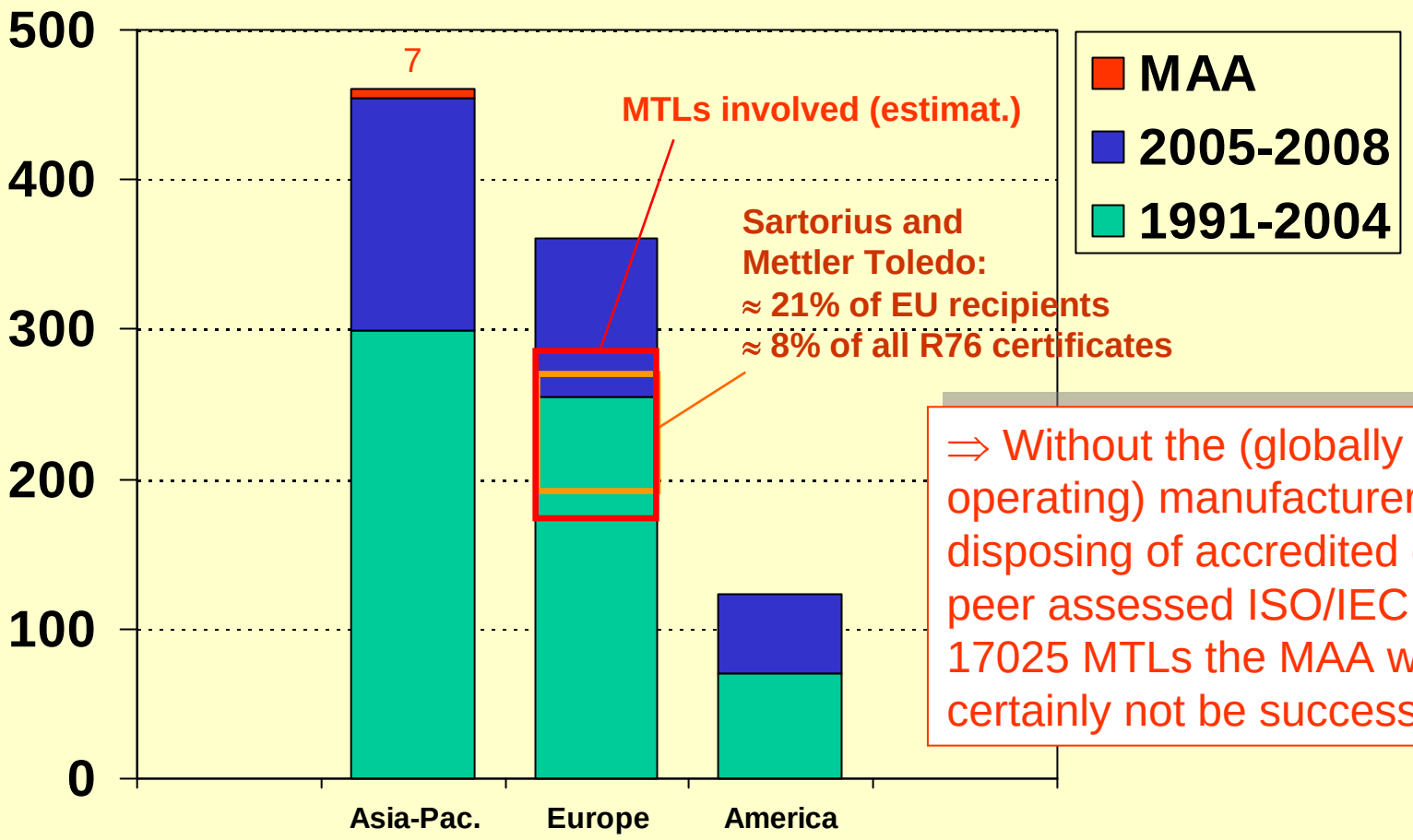


OIML Certificates (incl. Revis.) / Issuing Authorities



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

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



⇒ Without the (globally operating) manufacturers disposing of accredited or peer assessed ISO/IEC 17025 MTLs the MAA will certainly not be successful.

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

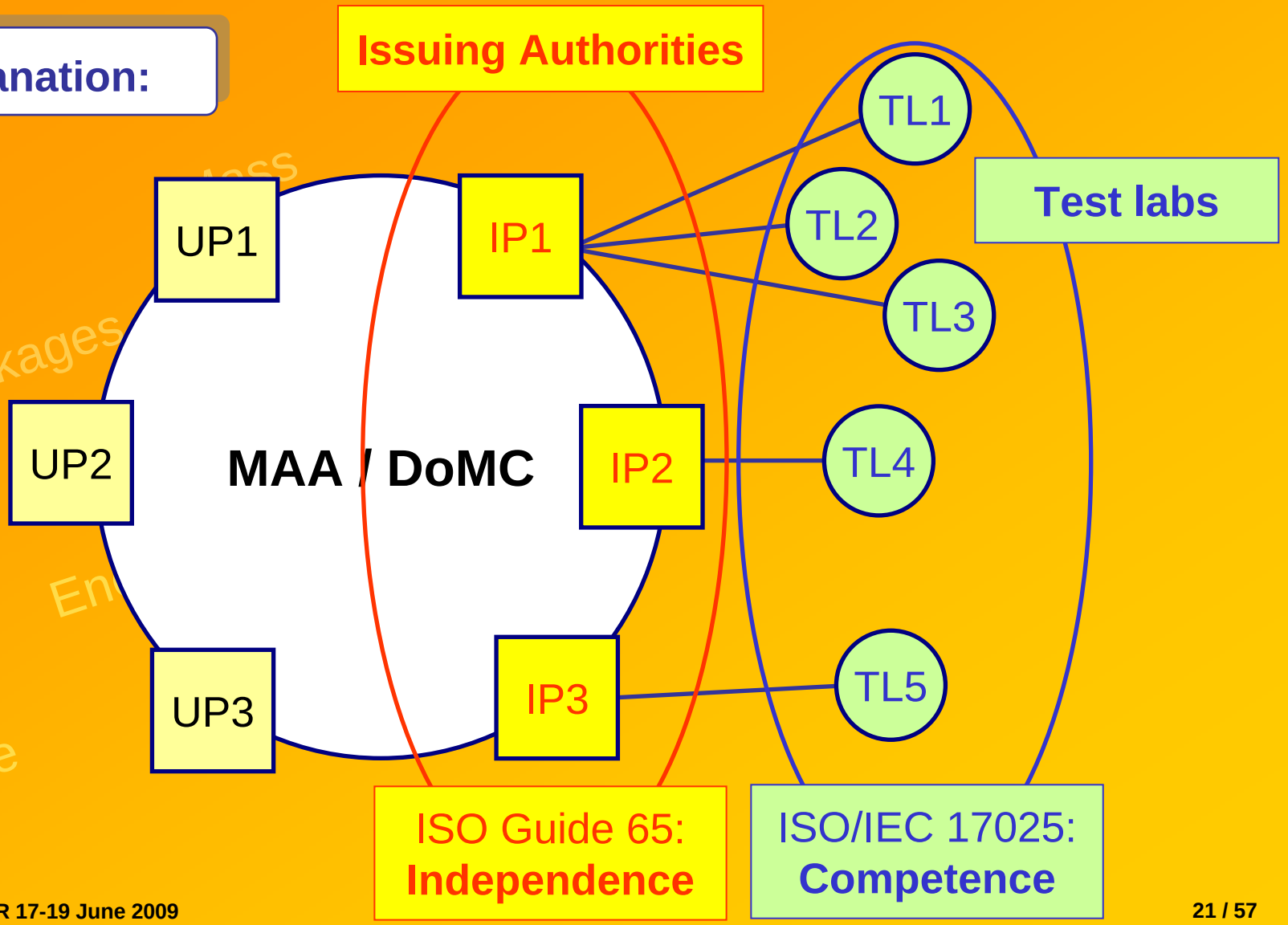
That means,

- 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:**

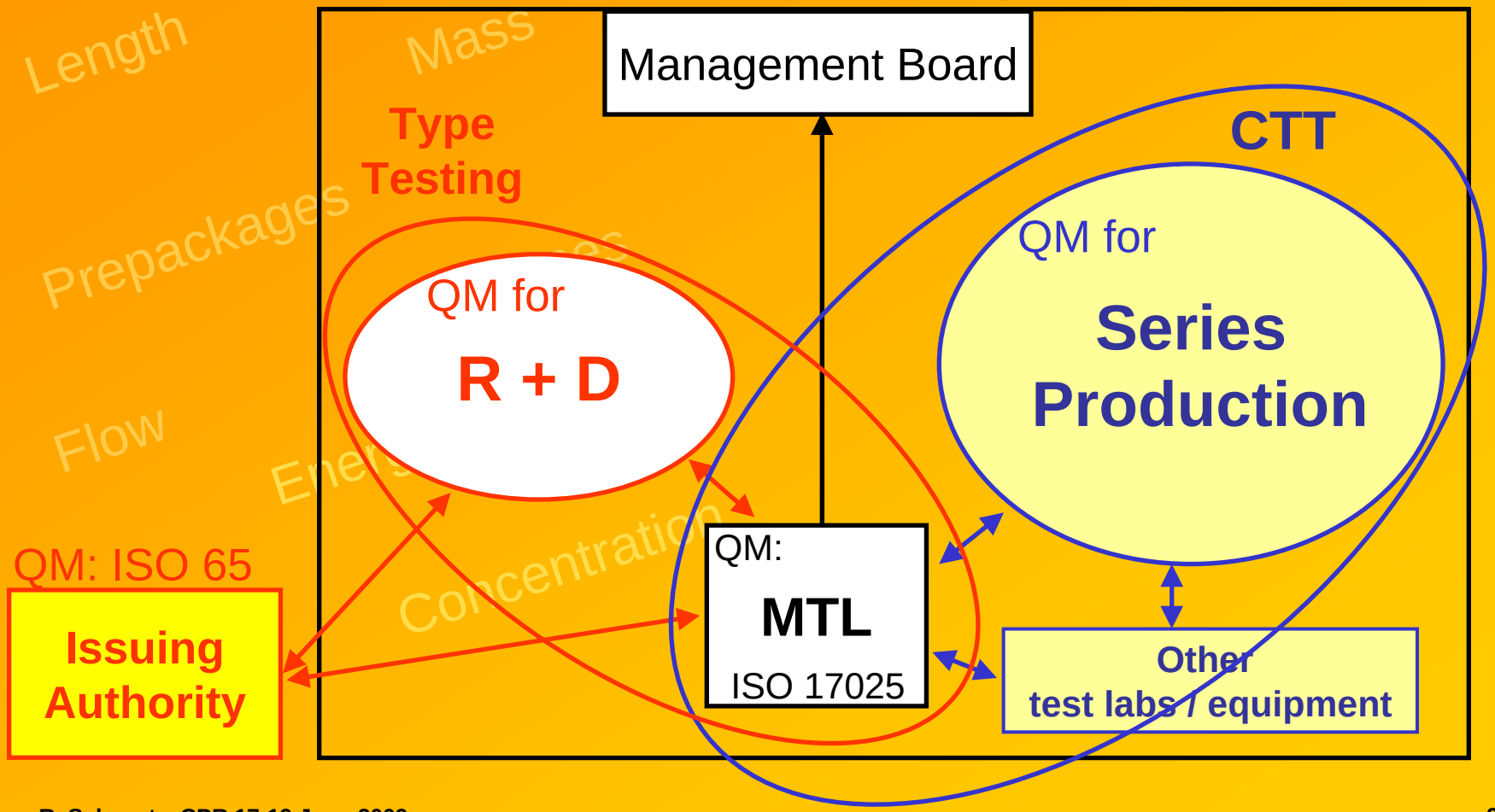
   This could be a problem with small companies not having implemented appropriate, acknowledged (e.g. ILAC accredited) and supervised QM systems for R+D, production control, etc.

   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 competion 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. & metro-logical 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 responsibles 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 ot 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 ot 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 ot 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 ot 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 ot 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 ot 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 ot 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 ot 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) EVPÚ, 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

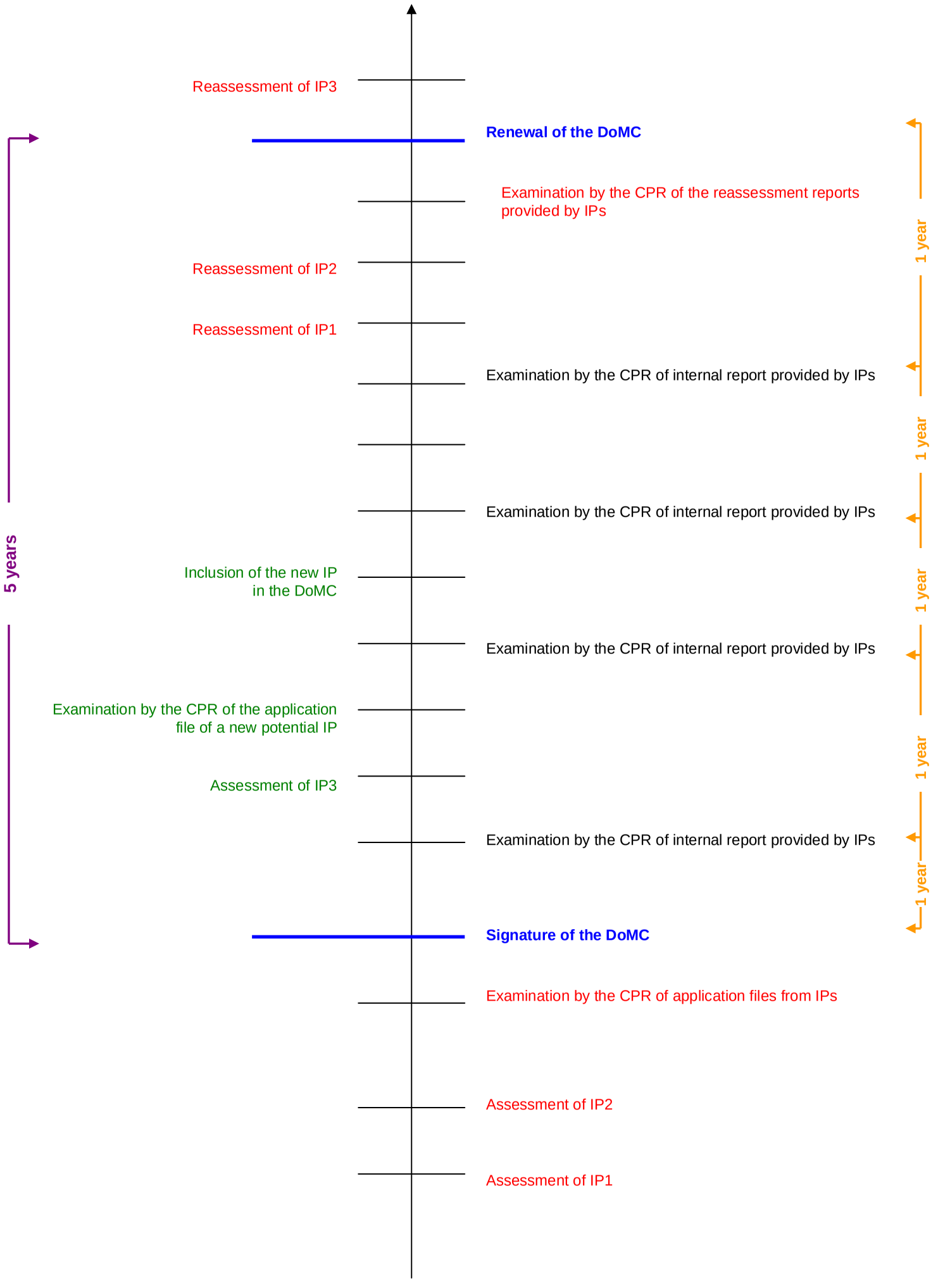
Use of Test Results from
Manufacturers' ISO/IEC 17025 Test Laboratories (MTLs)
within the Scope of the
OIML Mutual Acceptance Arrangement (MAA)

Thank you for your attention!

It's time for discussions!

ANNEX V

Revised maintenance scheme of DoMCs


Reassessment of IP3
Renewal of the DoMC
Examination by the CPR of the reassessment reports provided by IPs
Reassessment of IP2
Reassessment of IP1
Examination by the CPR of internal report provided by IPs
Examination by the CPR of internal report provided by IPs
Inclusion of the new IP in the DoMC
Examination by the CPR of internal report provided by IPs
Examination by the CPR of the application file of a new potential IP
Assessment of IP3
Examination by the CPR of internal report provided by IPs
Signature of the DoMC
Examination by the CPR of application files from IPs
Assessment of IP2
Assessment of IP1
5 years
1 year
1 year
1 year
1 year