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QUALITY MANAGEMENT OF TEST AND MEASUREMENTS RESULTS: FROM NATIONAL STANDARDS TO THE END USER

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Abstract: Quality is demonstrated by measurements. Therefore quality management of measurements and tests results is the cornerstone of the quality infrastructure. By now, the ISO IEC 17025 is well established as the best reference to provide effective quality management of test and calibrations results. To be effective quality assurance should be a continuum. The paper deals with practical steps and solutions implemented by NIM-Romania in order to provide the necessary quality from national standards calibration level to the customers offered calibrations one.
Keywords: NIM-s, MRA, CMC-s, quality systems.

1. INTRODUCTION

ISO IEC 17025 **[1]** is emphasizing on the outmost importance of assuring SI traceability of the tests & calibrations reported results via well characterized, recognized, national standards. To be really effective, the quality management has to adequately cover the whole dissemination chain, from SI to the end user. To put things as simple as possible here are the main levels of the units dissemination chains:

- SI to the national standards transfer;
- National standards to the (national) laboratory reference standards transfer;
- National laboratory reference to accredited and other laboratories reference standards transfer activities;
- Measurement devices

Obviously, meeting the quality requirements at different levels implies specific approaches. How things should be done for the first two levels, is thoroughly described in the CIPM-MRA documents **[2]** and in a lot of comprehensive guiding recommendations issued by the Regional Metrological (co-operation) Organizations **[3]**.

At the third level, where customer confidence is paramount, accreditation is more and more sought for.

2. NATIONAL STANDARDS LEVEL

2.1 General

As Euromet Guide nr. 1 clearly states, national institutes and laboratories are special cases; as designated national standards operators, their defining mission is the units representation and dissemination at national level, in full compliance with the CIPM-MRA requirements. Following a thorough evaluation process **[4]** their dissemination capabilities (CMC-s) are officially recognised and published as CMC-s in the Annex C of the MRA Key Comparison Data Base **[5]**. In this process one major requirement is that the national institute has implemented and operates a quality system according to the ISO IEC 17025 requirements covering the claimed capabilities (CMC-s).

Therefore quality management systems are a key issue in the global approach the CIPM-MRA is promoting. Currently all Regional Metrological (co-operation) Organizations (RMO) organized Technical Committees for Quality aimed at providing a stimulating framework for implementing ISO IEC 17025 based quality systems in the affiliated national laboratories.

General quality management issues are discussed and monitored within the RMO-s Technical Committees for Quality while technical issues are thoroughly analysed within the relevant Technical Committees of the RMO-s.

Based on this system of thorough review of the claimed CMC-s**,** the C Annex of the CIPM-MRA Key Comparison Data Base was drawn and continuously updated on the BIPM site. It is the result of a monumental work and it certainly represents the most comprehensive collection of reliable information on the existing calibration capabilities worldwide.

The CIPM-MRA key comparisons system provides a most effective framework to meet some of the most important requirements of ISO IEC 17025: SI traceability (by establishing the degree of equivalence of primary realizations) and demonstration of technical capabilities (CMC-s) to perform units transfer within specified ranges and with the claimed uncertainties.

2.2 Traceability issues

Basically there are two types of national standards: primary and secondary ones. For a primary standard, traceability is demonstrable with results obtained within CIPM Key comparisons **[6]**. If, from whatever reasons, this is not possible, comparisons with other primary standards already recognised is necessary.

For a secondary type standard, straight calibration against a recognised capability, within the CIPM-MRA framework is necessary.

2.3 Dissemination issues

From obvious practical reasons, demonstration of dissemination capabilities (CMC-s) from national standards is just as important as traceability. For primary standards, the results obtained in CIPM-Key comparisons also substantiate the related claimed CMC-s. For secondary type

standards, participation in the RMO key, supplementary and bilateral comparisons is necessary in order to substantiate the claimed CMC-s. Note however that RMO key, supplementary and bilateral comparisons do not provide traceability.

3. NIM-ROMANIA QUALITY SYSTEM STATUS

In order to improve the overall quality of it`s activity and to prepare for EUROMET **[7]** accession, during 2002 the NIM-Romania quality system **[8]** was drafted. It was implemented during 2003 and 2004. Following, during January 2004, the NIM-Romania quality system was presented to the EUROMET QS Forum 11-th meeting, organized in Lisbon **[9]**.

After detailed written and oral presentations **[10],** it was concluded that the NIM-Romania quality system is adequate and that the implementation in all laboratories should continue during 2004 **[11]**.

During February 2005, the EUROMET QS Forum 12-th meeting was organized in Bucharest, Romania's capital. This allowed the EUROMET QS Forum participants the opportunity to effectively screen the NIM-Romania quality system completion of implementation **[12]**.

According to the issued documents **[13]** the Quality visit was a success.

Currently all the NIM-Romania claimed / declared CMC-s are covered by the NIM quality system.

4. COMMERCIAL CALIBRATIONS ISSUES

4.1 NIM approach

Even if it they are of key importance, national standards level calibration capabilities is not of obvious/direct concern for the end users. Besides, even with flexible accreditation it would be difficult and expensive to adequately cover this level. Therefore, for the time being, at NIM-Romania, at this calibration level the quality management is performed under self declaration and no accreditation is sought for.

Meanwhile, since most of the customers are testing laboratories that work hard to do their job under accreditation, they naturally ask that, as provider of the calibration certificates for their reference standards, the NIM-s laboratories should also be accredited for the commercially offered calibration services.

That's why, for this level of activity, more and more national laboratories, (including NIM-Romania), seek accreditation. Following this trend, all the NIM-Romania laboratories contracted or are about to contract accreditations for the more important of their commercial calibrations.

4.2 Other test&calibration laboratories approach

For other test & calibration laboratories in the economy things are dealt with according to their customers requirements. More and more such laboratories get accredited on the basis of ISO IEC 17025.

SI traceability is provided by NIM-Romania or, if not possible, by external laboratories accredited by EA bodies **[14]** or by national laboratories, according to their CIPM recognised CMC-s.

Calibration capability demonstration at this level has some specificity; since participation to CIPM-MRA key comparisons is not possible, this requirement is met by participation to inter-laboratory comparisons or proficiency tests, organized according to ISO 43.

Up to now more comparisons of this kind were organised by NIM-Romania and many test & calibration laboratories belonging to the Romanian Bureau of Legal Metrology **[15]** took part in.

5. OTHER ORGANIZATIONAL STEPS

To provide the framework needed to meet the quality requirements at different levels of the calibration activity of NIM-Romania, other important internal steps were undertaken during 2005.

First, a national regulation importing the CIPM-MRA requirements for the national standards and associated calibration capabilities was drafted and adopted **[16]**.

Following, during 2005, a major contract aimed at meeting the CIPM-MRA requirements concerning the national standards and the associated transfer capabilities was signed with the Ministry of the Economy and Trade.

Besides significant improvements on equipment, it allowed dozens of Key Comparison participations and external, SI traceable, calibrations of the existing national standards.

Probably the best measure of the dynamics of this synergetic effort is given by the statistics of NIM-Romania participation in CIPM-MRA relevant activities organized within EUROMET: from less than 10 participations in 2001 to over 50 participations in different projects (traceability, co-operation and comparison projects) by mid 2006 **[9, 12]**.

6. ACCREDITATION OF NIM-s SPECIFICITY

Accreditation of national laboratories is rising, some delicate problems. That's because as EUROMET Guide 1 **[3]** clearly states, national laboratories, as operators of the national standards, are special cases.

Actually many of the national laboratories (including NIM - Romania) are "two in one" kind of: besides the section in charge with the national standards (following the CIPM-MRA recommendations), they also maintain complementary sections dedicated to units dissemination on commercial basis. The latest activity is obviously suitable for accreditation.

Dealing with the two activities in the same organizational unit is a delicate affair and it takes a lot of competence and good will from both the national laboratory and accreditation body sides. In the NIM-Romania case, the two accreditations performed by DKD at NIM during 2003 provided a very effective guide.

6.1 NIM laboratories accreditation status

During 2003, two of the NIM-Romania laboratories (Mass and Electrical calibrations) were accredited by the prestigious DKD **[17]**.

Currently, to better meet the customers demands, ten contracts funded by the Ministry of Education and Research and seeking accreditation were signed so that, by the end of 2007 all the NIM-Romania laboratories will be accredited for most of their commercial calibrations.

7. CONCLUSION

Quality management at the national standards level is thoroughly described in the CIPM-MRA and other documents **[1, 3]**. Basically they mean that a quality system according to ISO IEC 17025 requirements should be operated at the national standards level if CIPM-MRA recognition of the claimed CMC-s is sought for.

For commercial calibrations the same rules that apply for usual test & calibration laboratories should apply for the NIM`s.

After successful implementation of it`s ISO IEC 17025 quality system (2003-2004), NIM-Romania is currently completing a major contract aimed at fully meeting the CIPM-MRA requirements for the national standards it operates and for the related CMC-s.

For the commercial calibrations, accreditation is sought for in 10 projects contracted by different NIM laboratories with the Romanian Ministry of Education and Research.

Acting at both levels (national standards and commercial calibrations) NIM-Romania effectively supports the national quality infrastructure within the European integration process.

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