

G07.11 Position Paper Role and Responsibilities of DIs

TC-MC

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Introduction:

National Metrology Institutes (NMIs) have the prime responsibility of being the source of traceability of the highest metrological level to the SI, or if this is not yet feasible, to other internationally agreed references, for metrology users in their country. This comprises the development, maintenance and dissemination of national measurement standards traceable to the SI, or when this is not (yet) possible, to other internationally agreed references. A major part of this work is the international recognition of these measurement standards and of the calibration and measurement reports and certificates issued on the basis of internationally assessed and approved Calibration and Measurement Capabilities (CMCs) in accordance with the rules laid down and agreed in the CIPM MRA. In many countries the NMI shares this responsibility with one or more Designated Institutes (DIs) like the NMI operating at the top of the national metrology system. DIs play a crucial role in complementing the fields of activities of the NMI and bring in expertise in metrological areas not covered by the NMI, often in non-traditional fields of metrology, thus making an efficient use of the available national resources. Whilst a common understanding of metrological activities has been developed amongst NMIs over many years of fruitful and continuously convergent cooperation, in the case of DIs a much wider range of understanding and *modus operandi* may be observed. This paper, therefore, aims to provide a focused description of the activities that DIs are expected to provide within the framework of EURAMET. This also takes into account the criteria to be fulfilled in submitting CMC claims on the basis of the resolutions 28/1 and 28/2 of the 28th JCRB meeting, EURAMET Guide 10 and 11 as well as ILAC P10:01/2013. This information might be used as a guide providing key reference criteria in the decision process for a designation.

Situation of DIs in EURAMET:

- EURAMET currently has 71 DIs; this number will continue to increase.
- Many of the DIs are very small (e.g. a small laboratory within a larger organisation) and this risks "fragmentation" of the European metrology landscape
- Nevertheless, the use of already existing metrological capabilities and competences is in many countries the most sustainable and efficient way to cope with new demands for national measurement standards.
- The workload for the TC-Q in reviewing the QMS of NMIs & DIs is very high (with over 100 institutes participating) and constantly increasing.
- Maintenance of the CIPM MRA via the CMC recognition procedure is a highly resource intensive process. This represents a considerable burden to the RMOs and NMIs providing reviewers; expert time is provided at no charge.
- Financial aspects are becoming a key issue in most DIs (as well as NMIs)

Services delivered by NMIs and DIs for disseminating the SI (among others)

- Calibration of transfer measurement standards and measuring instruments and issuing of calibration certificates
- Certified Reference Materials (CRMs) production, including certification, traceable to the SI and, where not (yet) possible, to other internationally agreed references
- Capability to assign traceable values to "in-house" reference samples of customers

- Validation of measurement methods/procedures
- Reference value assignment of Proficiency Testing samples (for own PT schemes and/or third party PT schemes)

By this:

- Delivering metrological traceability to customers from industry and common welfare (e.g., clinical, environmental or food reference laboratories) including knowledge transfer
- Delivering metrological traceability to ILAC Arrangement accredited as well as non-accredited “calibration” and routine (monitoring, testing) laboratories, CRM producers and PT providers.

Taking into account the above mentioned, the following recommendations are made:

Criteria for a CMC related to a national measurement standard

In particular to be considered for the proposal of a new DI

- The CMC claim is related to an existing or intended service.
- The practical implementation of the service is demonstrated by being able to show for example existing cases of providing the service, certificates issued, etc.
- There is a clear and on-going commitment to provide the service on a long-term basis, treating all customers on an equal footing.
- The CMC provides a “dissemination of the unit” via calibration, value assignment or certified reference materials¹
- The service can be at primary, secondary (or even lower) metrological level, fit-for-purpose in the national metrological hierarchy. But it has to be the reference at the national level.
- As the national reference it represents the “connection” between the national metrology infrastructure and the international metrology system, described in the CIPM MRA, operating under the aegis of the Inter-Governmental Treaty of the "Metre Convention".
- The validity of a CMC is checked in accordance with the rules described in the CIPM MRA and criteria and guidance given by the JCRB and approved by the CIPM. This requires active participation in international intercomparison exercises organised by CCs or RMOs and attendance at meetings when comparisons are discussed.
- Criteria of complementarity: The CMCs offered by DIs should be complementary (in terms of measurands or ranges) but not overlapping to those of other DIs or the NMI in the country. It is the responsibility of the coordinating NMI or the national responsible authority for the national metrological infrastructure to guarantee the complementarity.

Realizing metrological traceability

Metrological traceability is defined as the property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.

¹ this may be also providing a reference value for PT schemes.

Its realisation should be achieved:

- Only by one's own primary realisation or via services offered by another recognized NMI/DI. Details can be found on specific CIPM documents published by BIPM.
- Traceability cannot come from a non-NMI/DI (accredited or not-accredited)
- Traceability cannot come from CRMs delivered by non-NMIs/DIs.
- A list with exceptions to this is proposed by the relevant CC, approved by the CIPM, and published by the BIPM
- Traceability is not realized by obtaining "satisfactory" results in a comparison or in a PT scheme, but PTs are very useful for benchmarking performance and creating awareness of measurement competence.

Designation process for Designated Institutes (DI)

- The designation is done by the authorised body of the country:
 - government/responsible ministry/authority, or
 - coordinating NMI, if authorized to do so by its government
- The scope of the designation must be specified. A contractual arrangement between the national responsible authority for the metrological infrastructure or the coordinating NMI, if this NMI is authorized to do so, and the DIs of a country on the scope of designation is recommended for this purpose.
- Institutes should only be designated if they:
 - hold and maintain (potential) national measurement standards, and
 - have appropriate metrological experience and scientific expertise and
 - will act as a NMI in a well defined area of metrology, and
 - will deliver traceability in a well-defined metrology area, on an equal footing basis to all its customers.
- Potential DIs should have already broad experience in accurate measurements in their field of designation and apply metrological principles, in particular with respect to traceability and measurement uncertainty. DI activities are on top, above and different from testing activities, consequently requiring different error budget analysis and appropriate quality systems!
- Designated Institutes must be prepared to:
 - invest in staff and equipment to support their designation;
 - train specialized metrological staff in charge of their metrological activities;
 - have appropriate laboratory space available, which will be equipped with national measurement standards and other relevant equipment, maintained at fit-for-purpose laboratory conditions;
 - participate in metrological research such as EMRP, EMPIR, etc.
 - participate actively in relevant RMO and Consultative Committee (Working Group) activities (comparisons and other activities)
 - develop and publish CMCs
 - disseminate units based on their CMCs
- The Director of a DI is welcome and expected at EURAMET General Assemblies, to represent all metrological fields
- DI experts are expected to actively participate in the relevant RMO TCs and, if applicable, in the relevant CCWGs and CCs

- The BIPM is not in a position to judge whether an officially announced designation of a DI is in compliance with all criteria for DIs. In the framework of the CIPM MRA the responsibility to check compliance with all criteria for DIs is assigned to the RMOs.
- The RMO concerned is responsible and is charged to carry out quality management system assessments, assessing whether the quality system is in compliance with ISO/IEC 17025 (calibration) and, if relevant, ISO Guide 34, and whether the claimed CMCs are covered by the QMS, in compliance with the scope of designation.
- If, after a reasonable period of a number of years, the DI has not made significant attempts to obtain CMCs, withdrawal as a DI should be considered²

Specific recommendation for EURAMET:

- To evaluate the capability and competence of a new DI, a technically oriented on-site visit by reputed, internationally recognized peers shall be carried out, as soon as a first CMC claim is ready for submission before presenting its QMS to the TC-Q (a “normal” quality project is not sufficient).
- To evaluate the capability and competence for a “new service” (NMI or DI) an onsite-visit by peers is recommended; the relevant TC should take a decision. The accreditation scope of the DI will be also taken into account, if relevant.
- To have a mutual exchange of information between NMIs and DIs regarding annual reporting to TC-Q and other relevant information.
- DIs should maintain regular interactions with their NMIs about their activities within the scope of designation as well as broader EURAMET and MRA issues
- DIs that intend to participate in European metrology research programmes are expected to develop and maintain CMCs and to actively participate in the evaluation process and in the mutual exchange of information described above.

² One could consider to accept the DI at its designation with a preliminary status. Once they have CMCs published, they get a permanent status, according to EURAMET e.V. Byelaws and Rules of Procedure