



To: **National Society Presidents and EFLM National Representatives
of EFLM National Society Members**

26 February 2013

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**Call for nominations for
three Full Member positions and one Young Scientist Member position
inside the new EFLM Working Group: Accreditation and ISO/CEN standards**

Dear President and National Representative,

According to a process of reorganization of the EFLM Committee on Quality and Regulations, the working on Accreditation and ISO/CEN standards (WG-A/ISO) was disbanded at the end of 2012 and a new one, with the same name but with different terms of reference, has been re-established under the chairmanship of Dr. Michel Vaubourdolle (FR).

The new WG terms of reference are in attachment.

Now, we are now seeking for membership as follows: three Full Member positions and one Young Scientist Member position (less than 35y).

The term of office will be for two years, from March 2013 to December 2014. The position could be renewable for other two more terms upon advice of the Committee Chair.

Procedure for applications

Nominations should be submitted using the attached application form. A brief plan of the applicant's contribution to the aims and objectives of the relevant Working Group has to be included in the form.

Together with the application, a short CV should also be submitted underlining the qualifications and prior experience and publications in the relevant area. Candidates have to be officially recommended by their National Society and a formal letter of support must accompany the application.

Please send the signed and scanned application electronically to the EFLM Office: Silvia Cattaneo - e-mail: silvia.cattaneo@ifcc.org.

Deadline for applications: **March 15, 2013.**

We look forward to hearing from you.

With kindest regards,

Wim Huisman
Chair - EFLM Quality and Regulations Committee

Encl.: application form

EFLM Committee on Quality and Regulations
Accreditation and ISO/CEN standards
Working Group (WG-ISO/A)

WG Chair: Dr. Michel Vaubourdolle (FR)

Terms of Reference

1. To represent EFLM and the interest of medical laboratories within EA, ISO TC212 and CEN TC140
2. To harmonize accreditation of medical laboratories
3. To educate and train assessors of accrediting bodies on the application of the specific standards of ISO15189 (in collaboration with C-ET)
4. To develop guidance documents for laboratories which support the translation and implementation of accreditation standards in practice.

Ad 1. EFLM is a registered stakeholder of EA (European cooperation of Accreditation). It is an active member of the EA Health Care Committee which meets twice a year. In this committee different aspects in relation with accreditation according ISO15189 are discussed: flexible scope, POCT, pre-analytical phase, measurement uncertainty and multi-side accreditation, time spent in assessment. Concerning flexible scope an EA guidance document is produced, but the way it is handled is quite divers. In relation to POCT it is important to stress the relation of the ISO22870 with ISO15189. In the pre-analytical phase it needs more attention when the sampling is not done by the laboratory. For the Measurement uncertainty it is important not to be strict metrological only. In this committee more than 20 National Accreditation Bodies are present and very few medical laboratory representatives. EFLM has already a liaison with CEN TC140. This will be renewed under their new rules. A liaison with ISO TC212 is planned. In both Technical Committees the relevant discussions about standards for medical laboratories take place, but especially in ISO, which has the lead in this process. It concerns not only ISO15189 but as well ISO22870 and documents related to accuracy of glucose meters, application of measurement uncertainty, and standards and guidance documents on many aspects. It is important to have access to these discussions in the phase when these are composed in working groups. This can be done as well through the National Standard Bodies, who are the members with voting rights. The input in both cases can be discussed and harmonized in the WG.

Ad 2. Harmonization of accreditation is one of the main purposes of this WG. It does so by the influence in the EA HC committee, but the point of view brought in by the representatives there is discussed in the WG. Apart from this information is gathered by questionnaires to the national societies, sometimes in collaboration with EA. Examples which already take place are the present status concerning accreditation in Europe and retention time of documents and samples. Possible other areas are use of POCT.

Ad 3. The value of accreditation is strongly dependent upon the assessment team, and especially the Technical Assessor. There is certainly a need for training and calibration. This should be done in cooperation with the C-ET but also with the Accreditation Bodies. A start to gather information concerning present situation is made.

Ad 4. Till now, the WG has not published guidance documents. It is planned to start with one for retention time. Sometimes there are legal obligations, but for many documents no clear guidance exists. Another possibility is to make a document concerning use of flexible scope. Again this will contribute to harmonization.