

Příloha č. 2

Draft minutes of WG Accreditation and ISO/CEN standards

Borea Room, Rixos Hotel, Dubrovnik, Croatia Sunday 08:00-08:15 on 14-10-2012

Present: Ludek Sprongl, Marc Thelen, Hans Wallinder, Christos Kroupis, Ines Vukasovic, J. U. Queralto, Pika Mesko, Jean Claude Libeer, Wim Huisman and Rob Jansen as observer.

1. *Opening.* It was a long time between today and the meeting in April last year in Berlin. Some information is send around in may this year.
2. *Draft minutes of the meeting 18-14-2011 in Berlin.* No comments and accepted
3. *Present situation concerning ISO15189 and other projects in TC212 of ISO.* Time for comments on the FDIS has passed. This was possible till 10 October. Very important that the Standard Bodies, which are the only institutes with a formal vote, of the counties represented in ISOTC212 vote a clear YES. Concerning the DIS draft of ISO15189 Sweden and Czech Republic voted NO, unless. In the meeting end 2011 all remarks were discussed and changes have occurred. **Especially for our colleagues in the mentioned countries it is important to influence the standard bodies.** In a discussion the importance of being present during these meetings of ISO TC212 was stressed. Decisions are taken there. New projects start there. To be present representing the vote of your Standard Body is preferable, but a professional present as a member of the delegation of the standard body ,joining of the working groups or task force which are initiated has a tremendous effect as well.. Unfortunately the presence of laboratory professionals, especially from the European countries is diminishing. At this moment a WG for the revision of ISO 22870 on POCT has started. Already about the scope of this revision we had to fight to maintain the present relation with ISO15189. Especially the UK tries to make the connection looser. This is the intention of UKAS and probably some others including the government over there. The convener is David Ricketts from UK which increase the danger. It is very important to influence the position of your standard body in the right direction and where possible to join this working group. Other working groups which started were on revision of ISOTS22367 concerning prospective actions based on risk analysis as intended for ISO15189; on making a sensible guidance document concerning uncertainty of measurement(this group is chaired by Graham White from Australia) ; and on making a guidance document for the pre analytical phase.
4. *Present situation in EA Health Care committee.* The discussion items were already mentioned in my recent paper in CCLM, which was send to all. The use of flexible scope is quite different in all countries. After a discussion it is decided that Marc Thelen will explain the developments in The Netherlands and that we will try to start a process of unifying the point view of our societies. It is preferable to include the testing by other laboratory specialists for instance microbiologists and certainly countries which cover the complete medical laboratory specializations. **A proposal will be sent around by Marc Thelen and a working group including France (Jean Philippe Brochet) will try to come with a combined view which can be discussed within the EA HC committee.** A draft proposal for accreditation according the present ISO22870 (POCT) was discussed within the EA HC. It is send for comment to the EFLM POCT Working Group. The procedure looks acceptable .It will be discussed in the next meeting in December. In this meeting in Zagreb as well the preliminary results of the Task Force on training and calibration of the assessors, based on a questionnaire send to all national accreditation bodies of EA, will be presented. The hope is that this will contribute to a better assessment. This will be discussed in the next meeting of our WG. The added value of accreditation according to ISO15189 is questioned in some countries. This is strongly dependent on the quality of the assessment. Information about evidence for the added value is quite welcome. It was discussed a couple of years ago in this HC committee, but if you know about some results in your country send it to me. Marc Thelen mentions that in the proposal of the ivd directive of the European Commission the need for being accredited according to ISO15189 is stated when doing home-brew testing. This in relation to the need for validation of our tests. In fact every modification of a test bought with a CE mark, makes it already a home-brew one.
5. *Retention Time.* Pika Mesko tells that the response is very low. Probably some countries have no strict policy for this. The possibility to get more results by involving the accreditation bodies is rejected. **It is decided that Pika Mesko and Ludek Sprongl will make a proposal about acceptable retention times for different documents, records and possibly samples.** The indicated times should be sensible and based on a risk management approach.

6. *Executive Board decision in restructuring EFLM.* A Procedures Manual was decided which makes things more hierarchic and restricts the amount of periods for members within a working group, committee or board. Apart from this, the Management committee is changed in a Management and Regulations committee. This has been done without consultation, and the communication was a mess. It has as a consequence that I will continue as the chair of this new committee. The present working groups of Accreditation and ISO/CEN Standards and on IVD will continue. Because of the restriction in terms all members of the WG accreditation have to be renewed. I will plead in the meeting this afternoon and tomorrow with the board for taking care of continuity and maintenance of competence. Flexibility in this is essential. Of course, corresponding members can stay and those countries not longer represented as member can nominate corresponding members.
7. *Other Business.* None. Besides we have exceeded the time with a quarter of an hour.
8. *Next meeting* will be in May 2013 during the Eurolab in Milan.

Note added after the meeting.

We have got flexibility in changing from the present to the new situation. Nominations for new members of WG Accreditation will be asked from the national societies and the interval of change will be done gradually.

Wim Huisman 19-10-2012