

Issue 2012—1

1 August 2012

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Editorial

It is our pleasure to present to you the first issue of the new EQALM Newsletter. The aims of the Newsletter is detailed in EQALM Newsletter: an introduction. This first issue includes interesting contributions on the activities of the working groups, a discussion group on accreditation, the AACC harmonization project and a literature review. Also preliminary information regarding the forthcoming EQALM symposium is provided.

We hope you appreciate this information and challenge you to actively participate in the communication between EQA providers. Any feedback regarding this newsletter is highly appreciated.

Editorial board

Board message

The scope of EQALM states that it should provide a forum for co-operation and exchange of knowledge on quality-related matters especially with regard to external quality assurance programmes in Europe. The intention of this newsletter is exactly that – to provide an exchange of knowledge. And of course by this exchange to make our EQAS schemes better and thereby improve the quality in medical laboratories. I am extremely happy by the initiative of the Editorial Board and I encourage all of you to use the Newsletter. And – I do look forward to seeing all of you in Herlev, Denmark in our yearly meeting.

Sverre Sandberg
Chairman EQALM

EQALM Newsletter: an introduction

Up to 2010, EQALM provided an international journal on Quality Assurance, called EQA News to all EQALM members and other parties interested in EQA. At least 2 issues were published annually, providing a total of 21 volumes of which the last 10 years' issues are available to download from the EQALM website.

EQA news included scientific publications covering Quality Assurance, cases studies and observations from EQA surveys, project and working group reports, Guideline developments and abstracts from the annual EQALM symposium. The success of EQA News relied upon the scientific contributions from EQALM members.

Over the last couple of years, there has been a steady decline in the number of contributions. One of the many reasons, was that authors, understandably, prefer to have their work published in peer-reviewed scientific journals included in PubMed. There are a wealth of scientific journals available for EQALM members which encompass quality assurance in laboratory medicine; EQA News has struggled to compete with these. For this reason, it was discussed both within the Board and the General Assembly last year as to whether it was feasible to continue with this publication in its current format.

It was clear that it was very important to maintain good communication links between the Board, EQALM members and other interested parties and it was therefore decided by the Board to change the format to that of a newsletter. Barbara de la Salle, Annette Thomas and Piet Meijer have volunteered to start-up this newsletter.

The aim of this newsletter is to facilitate communication between EQA providers and other interested parties on information related to External Quality Assurance in Laboratory Medicine.

The format of the Newsletter will be that of short articles and initial suggestions include the following categories: Working Group information, accreditation, EQA scheme issues, laboratory issues, meeting announcements, and literature reviews. It is not meant to include full peer-reviewed scientific papers but short snippets on interesting and "hot" topics. E.g. within the category "EQA scheme issues" this could include any interesting observation or issues you may have, any practical problems and how they were resolved. Relatively small contributions (250 – 500 words) are welcome. The Newsletter will also provide updates on on-going projects within the EQALM Working Groups.

The EQALM Board as well as the editorial board hopes that this newsletter can become an important communication tool between EQA providers.

The success of this newsletter depends not on the enthusiasm of the editorial board but on the contributions from EQALM members. We encourage you to share your ideas, your views, your issues, your successes, new developments, and make this newsletter a success.

EQALM symposium 2012

October 25th – 26th
Herlev Hospital, Denmark

*ISO/IEC 17043 – is it fit for purpose
for Medical Laboratory EQA Accreditation?*



For further information see page 4

A Roadmap to harmonisation of medical laboratory test results

It is well-known that for many medical laboratory tests the comparability of results between different methods is hampered. This is, for instance, seen in our external quality assessment (EQA) surveys for all kind of protein-based parameters and hormones.

In 2010 the American Association for Clinical Chemistry (AACC) took the initiative to brought together representatives from all different kind of scientific and governmental organisations, diagnostic industry and EQA organisations. On behalf of the EQALM Piet Meijer was delegated to this meeting. During 3 days a concept for a roadmap for harmonisation of clinical measurement procedures was intensively discussed. This results of this conference were published in a paper in *Clinical Chemistry* in 2011 [1]. This publication describes the background of this initiative, the organisational structure needed to initiate and conduct harmonisation as well as important technical issues that should be considered. At our last EQALM symposium in Szeged Gary Myers from AACC gave an excellent overview of this initiative. After his presentation we had a lively discussion on the role EQA organisations could play in the process of the harmonisation of measurement procedures. It was concluded that EQA organisation could play an important role. But one of the prerequisites for such a role is the use of commutable samples in our surveys.

After the 2010-meeting three different working groups were settled to further work on this initiative. The first working group focussed organisational aspects, the second working group focussed on the development of toolbox of technical procedures to achieve harmonisation for a measurand and the last working group focused on the development of checklists

needed for an inventory of potential candidate measurands for harmonisation.

Recently the three working groups had physically met during another three days working conference. It is expected that by the end of 2012 a complete new organisation is settled which will coordinate the initiatives for the harmonization of clinical laboratory measurement procedures.

It is evident, this is a very important initiative. It is also evident that EQA organization could play an important role both in the recognition of potential candidate measurement procedure for harmonization as well as in monitoring the effect of harmonization in clinical laboratory practice. It is therefore important that also within the framework of EQALM we should follow the developments of this initiative as well as to prepare ourselves for an active role in the process of harmonization.

1. Greg Miller W, Myers GL, Lou Gantzer M, Kahn SE, Schonbrunner ER, Thienpont LM, *et al.* Roadmap for harmonization of clinical laboratory measurement procedures. *Clin Chem*, 2011; 57: 1108-17.

Clinical Chemistry 57:8
1108-1117 (2011)

Special Report

Roadmap for Harmonization of Clinical Laboratory Measurement Procedures

W. Greg Miller,^{1*} Gary L. Myers,² Mary Lou Gantzer,³ Stephen E. Kahn,⁴ E. Ralf Schönbrunner,⁵ Linda M. Thienpont,⁶ David M. Bunk,⁷ Robert H. Christenson,⁸ John H. Eckfeldt,⁹ Stanley F. Lo,¹⁰ C. Micha Nübling,¹¹ and Catharine M. Sturgeon¹²

Literature Review

Comparison of different approaches to evaluate External Quality Assessment Data

Wim Coucke ^{a,*}, Bernard China ^a, Isabelle Delattre ^a, Yolande Lenga ^a, Marjan Van Blerk ^a, Christel Van Campenhout ^a, Philippe Van de Walle ^a, Kris Vernelen ^a, Adelin Albert ^b

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Clin Chim Acta 483 (2012): 582-586

This paper will be of interest to EQA organisers and statisticians, as it gives an objective evaluation of five of the key methods commonly used to calculate z scores. Using randomly generated sets of data of different sizes, with single outliers added, Wim Coucke examined the Grubbs and Dixon outlier exclusion methods, and the Tukey, Qn and the ISO algorithm robust statistic based methods. According to this study, there is little difference in the choice of method for larger sample sizes, especially when the outlier is distant from the target value. However, it is not uncommon to have to use peer groups of less than 10 in EQA programmes with a small participant base, to overcome the impact of matrix effects, and, under these circumstances, the choice of method is important. For these small sample sets, the study suggests that the outlier exclusion methods, particularly that of Grubbs, perform better than the robust algorithms, although the performance of any method varied to some extent depending on how far the outlier was from the target. If a robust method is preferred, the paper favours the Tukey method for small sample sizes. The method of generation of the data in the study (Normal and Student t-distributions) had no effect on the outcome. The paper focuses on small sample numbers, with just one outlier, and a note of caution is sounded over the presence of more outliers, as would be expected as sample size increases, which may require modification of the outlier exclusion methods to avoid the masking of a small outlier by a larger one. The information in this paper illustrates how important the choice of statistical method by the scheme organiser is in successful scheme design.

Working Group Messages

During the EQALM symposium in Szeged last year the 6 different Working Groups of the EQALM have met. Here a short summary of the ongoing activities of these working groups are given.

Microbiology (chair: Kris Vernelen):

The WG discussed homogeneity and stability of parasitology samples. A questionnaire had been distributed during the summer. The WG had agreed to re-send the questionnaire to improve the numbers of respondents. It was suggested that the Questionnaire be added as a link on the EQALM website. All members were encouraged to participate in the questionnaire.

Haematology (chair: Joan-Lluis Vives Corrons):

There are 3 ongoing projects:

1. An European Survey of existing EQAS for rare disease diagnostic tests (lead - Barbara de la Salle)
2. Harmonisation of CBC reference ranges or acceptance limits for EQAS in Europe (lead -Stephanie Albaredé & Barbara de le Salle)
3. Post analytical automated haematology Schemes. (lead – Anne Christin Breivik)

Virtual Microscopy (chair: Xavier Albe)

There are 2 ongoing projects:

1. A questionnaire was ongoing to provide an index of EQA Schemes using (or proposing) virtual microscopy.
2. Identification of volunteer organisations.

Haemostasis (chair: Piet Meijer)

There are several ongoing projects:

1. INR Project: completed, publication in process.
2. Reconstitution of lyophilised EQA samples: - completed, publication in process
3. Data Trial – Additional evaluation , publication proposed.
4. POCT-INR – accepted by CCLM for publication
5. Post Analytical INR Survey – submitted for publication
6. Pre analytical variables in Hemostasis. Project proposal will be written and a working group established.



Frequency (chair: Christel van Campenhout/ Annette Thomas):

An action plan for 2012 had been agreed with agreed lead for the 3 projects.

1. Gather the evidence to determine whether greater frequency leads to improved performance.
2. Gather evidence as to whether multiple samples are more effective than single or few samples. Gather evidence as to whether intervention and education leads to improvement in performance

Nomenclature (chair: Gunnar Nordin):

The following actions are ongoing

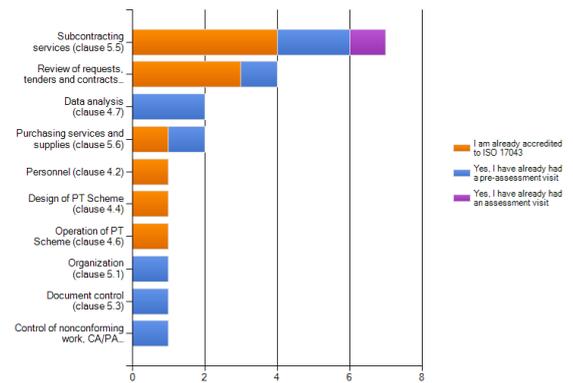
1. Pilot project in Haematology with support from Haematology WG
2. A database structure containing the information needed
Consider future maintenance of the database

If you are interested in one of the mentioned projects you can contact the chair of the working group via the EQALM office.

ISO 17043 Discussion Forum

The results of the questionnaire undertaken last year on EQA Accreditation, highlighted that our members were at quite different stages, with some having already achieved accreditation to ISO 17043 whilst others would be undertaking it in a few years time. The questionnaire also highlighted the more challenging areas of the standard. The Board have therefore decided to set up a discussion forum on the EQALM website where we can all share ideas and success stories, identify problems with the implementation of ISO 17043, provide solutions to more challenging issues and so that other EQA Scheme could learn from those that had already gained accreditation.

Which clause(s) in ISO 17043 do you feel was (or is going to be) the most difficult to achieve?



Programme EQALM Symposium 2012

Thursday 25 October (8.00—12.30 hr)

Working group meetings

Thursday 25 October (13.30—18.00 hr)

Session: Statistics in accordance with ISO/CEI 17043 – a practical approach.

Session: Homogeneity and stability in ISO/CEI 17043 – a practical approach

Session: Contract with subcontractors – one of the most difficult standards in ISO/CEI 17043 ?

Adam Uldall Lecture

Databases on biological variation: How are they established and how can they be used (Dr. Carmen Ricos)

Friday 26 October (9.00 —12.30 hr)

Session: How to run a perfect EQAS?

Contributions from Working Group projects

Abstracts

Friday 26 October (13.30 —15.30 hr)

EQALM General Assembly

Abstract submission

After the success of last year's session we are again offering an opportunity for members to present any new ideas or learning bytes to share with us.

Please submit an abstract (max. 500 words) using the following link. You may submit more than one abstract.

<http://www.eqalm.org/sites/default/files/AbstractEQALM2012.pdf>

A selection of abstract authors will be invited to provide an oral presentation. If you wish to submit an abstract but do not wish to be considered for oral presentation, then please let us know. Delegates who were unsuccessful in being selected for oral presentation will have the opportunity to display a poster of their work at the meeting.

Abstracts should be submitted before 1st September 2012 and sent to Sverre Sandberg (Sverre.sandberg@isf.uib.no).

We would like to welcome all of you at the 2012 EQALM symposium in Herlev, Denmark.

Please register as soon as possible via the EQALM website.
www.eqalm.org

Data Trial Project (Working Group Haemostasis)

Call for participation

Within the Working Group of haemostasis is project is running on the comparison of statistical procedures used by different EQA providers. Several EQA providers participate already in this project.

Participants will receive a data file including results for Prothrombin Time and INR and are asked to evaluate these "survey data" according to their standard statistical procedure used in their EQA programme. In addition a short questionnaire is provided. If you would like to participate please send an e-mail to Piet Meijer (P.Meijer@eact.nl) before **1 September 2012**. You will receive accordingly the data file and questionnaire. You are kindly asked to return the results of the evaluation before **1 October 2012**.

The results of this project are presented at the EQALM symposium in Herlev.

Meeting Calendar

4th—5th September 2012

UKNEQAS for Blood Coagulation - Annual Scientific Meeting - Sheffield, United Kingdom
www.ukneqasbc.org

25th—26th October 2012

EQALM Symposium - Herlev, Denmark
www.eqalm.org

8th—9th November 2012

ECAT Foundation - Haemostasis Symposium - Leiden, The Netherlands
www.ecat.nl

Next Issue

Contributions for the next issue of this Newsletter can be sent to the EQALM office before **15 November 2012**.

Also announcements of meetings organised by EQA providers for the period December 2012 - June 2013 are welcome.

The next issue of the Newsletter is scheduled for 1 December 2012.