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European Committee for External Quality Assurance Programmes in Laboratory Medicine

Activities in EQALM

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Labkvalita 2009-05-25

What is EQALM ?

The European Committee for External Quality Assurance Programmes in Laboratory Medicine

An umbrella organisation for organizers of EQA.

Started in 1990, after initiative from Adam Uldall, Denmark.

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38 members

- Full members: 29
- Individual members: 6
- Associate members 3

Members are e.g. Labquality, SEEK, Instand, DGKL, Equalis

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Who can be a member ?

Full Members of EQALM are ***not-for-profit organizations*** (which can appoint individuals) for External Quality Assurance - EQAssurance - programmes in laboratory medicine, which have ***national or substantial regional coverage*** in European countries (as defined by WHO). They have a strong ***liaison with the medical laboratory profession*** by including them in their steering committee or board.

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The annual EQALM meetings

- Dusseldorf (Germany) 1996
- Versaille (France) 1997
- Karlovy Vary (Czech Rep) 1998
- Florence (Italy) 1999
- Borås (Sweden) 2000
- Prague (Czech Rep) 2001
- Paris (France) 2002
- Barcelona (Spain) 2003
- Vienna (Austria) 2004
- Rome (Italy) 2005
- Geneva (Switzerland) 2006
- Amsterdam (Netherlands) 2007
- Birmingham (UK) 2008
- Berlin (Germany) 2009

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Other activities

- Publication of EQAnews
- Working groups on specific topics
- Participate in EEE (Eurachem, Eurolab, EA) working group for proficiency testing

What is EQA?
(Interlaboratory comparisons, proficiency testing)

- **interlaboratory comparisons** organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

DIS ISO-IEC 17043
Conformity assessment — General requirements for proficiency testing

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Comparable EQA for various sectors?

What is the fat content?

What is the cholesterol?

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Are you **looking for** quali
in the **dairy i**
Are you looking for an authority that cert

Supervision EU-hygiene Regulations
EC-approval based on COKZ-inspections
Approved dairy companies
Approved laboratories

Export certificates
to apply for a certificate
Health Certificates
Analysis Certificates
Veterinary Certificates

Advice on legislation and regulations
Dairy Legislation and Regulations
Labelling

Supervision Regulations Farm Milk
Supervision

EQA is very regulated in many areas!

NETHERLANDS CONTROLLING AUT
FOR MILK AND MILK PRODUCTS

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

In the medical field we have an European Standard for monitoring of IVD - products

May 2004

ICS 11.100

5 Requirements for organisations conducting EQAS

5.1 An EQAS shall be conducted by a competent organisation established in the field of medical laboratory examinations.

5.2 The EQAS organisation shall have an independent medical and scientific advisory committee.

5.3 The EQAS organisation shall be free from any commercial, financial or other conflicting interests - whether internal or external - which might influence its independent judgement or adversely affect the quality of work.

NOTE National authorities can state additional requirements for the qualification of the EQAS organisation.

— scheme design and organisation;

— identification of procedures (IVD MDs) used by the participant;

— classification and evaluation of data.

NOTE External quality assessment data generated according to these criteria will help manufacturers, users or competent authorities to monitor independently the post-marketing performance of IVD MDs.

This European Standard does not specify ways in which EQAS themselves are organised, nor how the individual or collective performance of clinical laboratories is evaluated.

Medical EQA

- In most countries not as regulated as EQA in other areas
- Focus on educational aspects and quality improvement
- Regional comparisons have practical impact on patient care

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Is medical EQA different from other EQA?

- Yes,
  - The participation is not as regulated as in many other areas
  - The use of human tissues as sample material very regulated

- But the same procedures fits all EQA organizers: the new ISO 17043

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DRAFT INTERNATIONAL STANDARD ISO/IEC 17043

CASCO

Secretariat: **ISO/CS**

Voting begins on
2008-11-13

Voting terminates on
2009-04-13

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION
INTERNATIONAL ELECTROTECHNICAL COMMISSION • МЕЖДУНАРОДНАЯ ЭЛЕКТРОТЕХНИЧЕСКАЯ КОММИСИЯ • COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

Conformity assessment — General requirements for proficiency testing

Évaluation de la conformité — Exigences générales pour les essais d'aptitude

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EQALM Working groups

- ISO 17043 – a mirror group
- ‘Frequency of participation’ in EQA schemes
- Haemostasis
- Nomenclature of measurement procedures
- Microbiology
- Virtual microscopy
- Haematology

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Concerns within the EQALM mirror WG

ISO 17043 does "not support the EQALM constitutions":

- ***not-for-profit organizations***
- ***national or substantial regional coverage***
- ***liaison with the medical laboratory profession***

But no contradiction!

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EQALM WG on ”Frequency of distributions”

Main topics

- What is the optimal frequency of EQA participaition?
- What is the optimal number of challenges in a survey?
- Is the same frequency and number of samples optimal for all participants?

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WG on nomenclature for measurement procedures

Main topics

- Statistics between organizers should be comparable.
  - The same statistical procedures.
  - The same nomenclature of the procedures used.
- Not yet an agreed terminology for procedures. A task for
  - EQA organizers ?
  - EU authorities ?

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EQALM WG
Virtual microscopy

Main topics

- Share experiences with different technologies. What is best practice and state of the art?

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EQALM WG Haemostasis

Main topics

- Are results for PK(INR) comparable in European countries?
- Are results from Owen and Quick comparable?

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Each laboratory has received a set of 4 different plasmas, two samples with an INR of 2.0 - 2.5 and two samples with an INR level of 3.0 - 3.5 INR.

- **Sample 1: Single plasma, low INR range**
- **Sample 2: Plasma pool, low INR range**
- **Sample 3: Single plasma, high INR range**
- **Sample 4: Plasma pool, high INR range**

Plasma pools were prepared from at least 10 different donors. The sample were prepared under supervision of Tim Woods at the UKNEQAS, Sheffield, United Kingdom.

	Sample 1	Sample 2	Sample 3	Sample 4
	Mean	Mean	Mean	Mean
Netherlands	2.15	2.53	3.09	3.27
Belgium	2.17	2.56	3.19	3.32
France	2.19	2.60	3.23	3.33
Romania	2.06	2.39	3.01	3.08
Germany	2.17	2.52	3.11	3.25
Croatia	2.20	2.53	3.09	3.28
Denmark	2.09	2.59	3.05	3.32
Sweden	2.03	2.53	2.98	3.20
Norway	2.03	2.50	2.92	3.18
Finland	2.00	2.54	3.11	3.25
ANOVA	P < 0.001	P = 0.018	P < 0.001	P = 0.001

	Sample 1	Sample 2	Sample 3	Sample 4
	CV (%)	CV (%)	CV (%)	CV (%)
Netherlands	7.9	9.5	8.1	9.5
Belgium	6.5	7.8	8.8	8.4
France	4.3	5.0	5.3	4.8
Romania	12.1	10.9	21.3	13.0
Germany	6.9	7.9	7.1	8.3
Croatia	5.5	6.3	7.4	6.7
Denmark	6.2	7.3	8.2	7.8
Sweden	4.4	5.1	5.7	5.6
Norway	7.4	8.8	8.2	9.1
Finland	6.0	4.3	4.5	5.2

EQALM WG Microbiology

Main topics:

- How can surveys in Microbiology be developed?
- Pre-analytical aspects specific for Microbiology

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WG haematology

Main topics

- Smear preparation and distribution
  - Two papers published
- EQA of haematology instrument and post-analytical EQA

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Next EQALM symposium July 1st -2nd 2009 in Berlin

- ”10 years after” the Stockholm conference
  ”Strategies to set Global Quality Specifications in Laboratory Medicine” (Kenny, D., C. G. Fraser, et al. (1999). "Consensus Agreement." Scand J Clin Lab Invest **59(7): 585.)**
- Still Consensus on Consensus?

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Still Consensus on Consensus?

- Analytical quality specifications based on
  1. Clinical outcomes
  2. Effect on clinical decisions based on
     1. Biological variation
     2. Clinicians' opinions
  3. Published recommendations
     1. International experts
     2. Local experts
  4. Performance goals set by
     1. Regulatory bodies
     2. EQA organizer
  5. Goals based on current state of the art
     1. From EQA data
     2. From publications

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- Thank you for the attention!

- www.eqalm.org