

# **EUROLAB NEWSBRIEFING**

## January - March 2015

## **Foreword**

Dear EUROLAB Members,



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Please find below the first EUROLAB Newsbriefing for this year informing you about some developments relevant to the Laboratory sector in the first quarter of 2015. As I indicated at the end of last year a lot of new developments and challenges are expected this year. So we must enter it with refreshed minds and full of enthusiasm and energy. We are already in the process of the revision of ISO IEC 17025.

First meeting of ISO CASCO WG 44 was held in Geneva from  $10^{th}$  to  $12^{th}$  February and it is rather early for evaluation. The areas drawing attention are as follows:

- Structure of the standard
- Process approach
- Role and position of ISO 9001
- Sampling as a standalone activity

Generally, EUROLAB representatives in WG 44 got rather good attention and feedback on EUROLAB Cook Books and White Paper – although none of them were discussed during the (official) meeting.

Another issue is the development of the ILAC document on handling tests and measurements performed within inspection activities. A first draft of this document has been discussed and new version will be negotiated in April focusing on the following:

- The document should constitute guidance to accreditation bodies on how to handle tests and measurements performed as part of accredited inspection. Scheme owner considerations should be tuned down.
- The question is not when one or the other standard should be used. The appropriate standard is always ISO/IEC I 7020 and all requirements therein always apply, but under certain conditions relevant requirements of ISO/IEC I 7025 also apply.
- The bridge between ISO/IEC 17020 and ISO/IEC 17025 is clause 6.3.1 of ISO/IEC 17020, but perhaps also other clauses
- What requirements in ISO/IEC 17025 that may possibly apply (method validation, measurement uncertainty, proficiency testing) should still be identified and described, but this is not the primary focus of the document.
- More important is to identify when these requirements do apply (methodology).
- The standard context description should be background material, but should be retained.
- Examples applying the methodology (case studies) should be included.
- Guidance on the formulation of non-conformities should be included.

You noticed special briefing from our meeting with representatives of DG Growth. Personally I am very satisfied with the outcomes of that meeting and with mutual interest in exchanging views and information. It is my belief that subsequent meetings at expert level will continue on topics discussed. Some preparatory steps have already been done.

Among others the mechanism of Regulation 765/2008/EU which uses the ISO/IEC 17000 series as harmonized European standards was discussed in relation to the fact that the content of these standards can substantially change as a result of their revisions and discussions / voting worldwide. Through this the European system can be influenced from outside Europe and changes might not always be positive from European legislation point of view.

We are in full preparation for the coming EUROLAB General Assembly which will be the special one as we will all celebrate the 25<sup>th</sup> Anniversary of establishing Eurolab. A special booklet issued for this Anniversary will mark the history of EUROLAB giving the floor to all past presidents and I should say also including me as after this GA I will extend the list of past presidents.

Another important document under development is the EUROLAB Annual Report 2014. I think that this is a good step to increase the visibility of EUROLAB and it is something real in this virtual world which you can hand over to your counterparts in negotiation. I distributed many Annual Reports 2013 invarious meetings and I can confirm that they always attracted attention.

Finally on a personal note my participation in EUROLAB matters started in the year 2000, as an observer in TCQA for Czecholab at that time, continuing in membership till now. Since 2003 I had been attending GAs as a President of EUROLAB-cz, Board meetings from 2006, being Vice-President from 2009 and the President from 2011 until now.

Now, I am leaving EUROLAB officially but still being ready to act as the past president and ensure continuity of our work and memberships. The current EUROLAB Board is good team of dedicated people with good professional backgrounds. As elections to the Board are coming up, new candidates should show you in which professional area are they competent how are they going to complement the current Board and you should then make your choice by voting. The future of EUROLAB is in your hands

I will always remember so many nice friends who volunteered to work for years for the success of the laboratory community. Some are saying that leaving is like dying. Hopefully I am not going to die but I am leaving here with you a piece of my life, my work and piece of my heart, wishing EUROLAB good Presidents, dedicated and professionally sound Board members and Chairs of all committees and last but not least, active, and satisfied members. For the future, I remain active at the EU level and it would be my great pleasure to assist EUROLAB whenever a need may arise.

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Yours faithfully

Jiří Sobola

President EUROLAB

# **EUROLAB** meeting with the European Commission, DG for Internal Market, Industry, Entrepreneurship and SMEs (DG GROWTH)

## Participants on behalf of the European Commission:

Mrs Valentina Superti (Director – Single Market for Goods)

Mr Daniel Bunch (Deputy Head of Unit - Internal Market and its International Dimension)

Mrs Nike Boennen (Policy Officer - Internal Market and its International Dimension)

Mrs Norma Mcgovern (Internal Market for Goods and Market Surveillance - Administrative Coordination Assistant)

#### Participants on behalf of EUROLAB aisbl:

Mr Jiří Sobola (President)

Mr Alvaro Silva Ribeiro (EUROLAB Board member)

Mr Drewin Nieuwenhuis (Secretary)

Ms Laura Martin (Junior International Affairs Manager)

EUROLAB had a meeting with the European Commission, DG for Internal Market, Industry, Entrepreneurship and SMEs on 4th February 2015. The meeting started with a short introduction of EUROLAB, given by Mr Jiří Sobola and Mr Drewin Nieuwenhuis on EUROLAB's main activities, objectives and priority areas of focus for 2015.

The discussions continued with the current issues of concern for EUROLAB and DG GROWTH and the legislative developments in the following key areas:

- The General Product Safety Directive (GPSD) The European Commission proposed a new Product Safety and Market Surveillance Package, following the public consultation on the revision of the current directive. With a new package of legislative and non-legislative measures the European Commission wants to improve consumer product safety and to strengthen market surveillance of products in the EU. The package is being discussed in the European Parliament and the Council of the EU. The European Commission has as main objective for the coming period to arrive to a common consensus on critical issues such as Article 7 Indication of Origin on which a study is currently conducted.
- <u>The Blue Guide</u> There were follow up discussions related to the latest revised version of the Blue Guide. For the coming period the European Commission has no intention to extend the scope of the Blue Guide to some other specific areas which are currently not covered. (e.g. construction products)
- The Medical Devices Directives The Medical Devices Directives are currently under revision, awaiting Council 1st reading position / budgetary conciliation convocation. The industry recognises the need to modernise and strengthen the current medical devices legislation in Europe by strengthening the Notified Body system and pushing to an increased EU Member States coordination. The main objective is to develop an overall regulatory framework which looks towards the future and which guarantees rapid market access for innovative medical devices to the benefit of patients, whilst at the same time offering the highest possible levels of safety by means of intensified control activities.
- <u>Accreditation and Standardisation</u> According to the Regulation (EC) No 765/2008 which embodies the European accreditation policy in relation to conformity assessment, there is only one Accreditation body per member state, requirement that is welcomed by the EURO-PEAN laboratory community. The main concerns are the different views on the other side of the Atlantic, where free competition is strongly supported. In Europe Accreditation Bodies can accredit only to harmonised European standards, requirement which does not apply outside the EU. Thus, EUROLAB put forward these issues to the European Commission, asking for their support in the future development of ISO standards and in the revision of ISO 17025 in particular.
- Validity of notifications in Nando EUROLAB understands that for entities directly involved in notification, it is important to know when certain accreditations that are linked to notifications expire. EUROLAB suggested to the European Commission to reconsider the publication of the date of expiry in the public domain of Nando as this can give a misleading impression to clients seeking to select a Notified Body (NB) and might lead to market distortion. Considering the above reasons, the expiry date can be made available in the members' area only.

As an overall conclusion, there is a general political consensus for the need to improve the market surveillance system and better implement and enforce the legislation already in place and make CE marking stronger, which EUROLAB has supported. The European Commission welcomes a closer cooperation with EUROLAB considering future exchange of views and opinions collected by EUROLAB from the labora-

tory community.





# EUROLAB meeting with the European Commissioner for Justice, Consumers and Gender Equality, Ms. Věra Jourová

The EUROLAB President, Mr Jiří Sobola, had a meeting with the European Commissioner for Justice, Consumers and Gender Equality, Ms. Věra Jourová, on 12th March 2015, in Brussels.

The meeting started with a short introduction of EUROLAB, given by Mr Jiří Sobola and continued with further discussions on:

- The role of stakeholders in cooperation with accreditation bodies and EA
- Product Safety and Market Surveillance Package
- The promotion of third party where the content and the conclusions of the CEOC, EUROLAB and IFIA Safety Seminar were very much appreciated
- The Transatlantic Trade and Investment Partnership (TTIP)
- Common areas of interest and possibilities of cooperation with DG Justice
- CEOC International EUROLAB IFIA Safety Seminar 2015 where Ms. Věra Jourová was kindly invited The meeting took place in a positive and constructive atmosphere.





## **EUROLAB** meeting with United Nations Industrial Development Organization (UNIDO)

The EUROLAB President, Mr Jiří Sobola, had a meeting with the representatives from UNIDO on 18th March in Vienna. The meeting was organised under the format of an awareness seminar for UNIDO staff who offer assistance for developing countries in the area of establishing sound quality infrastructure, accreditation systems in particular.

### **Topics discussed:**

- Accreditation and its role in regulatory area
- The need for involvement of stakeholders in accreditation issues,
- Quality infrastructure including market surveillance and customs services ,
- Balancing private and governmental CABs,
- The Eurolab position to the revision of ISO 17025,





## National Members' News

## **BMTA** News



## **BMTA Events Programme for 2015**

Promoting measurement and testing - speaking with one voice to Government, UKAS and the European Laboratory Community 4 February 2015 – Medical Laboratory Accreditation Workshop, Leeds

This is the third in a series of workshops on the implementation of ISO 15189 which BMTA has held in conjunction with UKAS. All three workshops have been sold out and a fourth is

planned later in the year – see below.

#### • 17 March 2015 – Instrumentation, Analysis and Testing, Silverstone

BMTA is organising a Forum entitled 'Metrology – Saving Time, Money and Tempers and Reducing Waste' at this annual event of the Engineering Integrity Society. The Forum presenter is Nick Turner of Coventry University with contributions from BMTA and UKAS. BMTA will also have an exhibition stand at this event.

• 23 April 2015 – Measurements in Advanced Manufacturing (3), Glasgow

In the third in a series of seminars, BMTA is working with the AFRC to run a seminar and table top exhibition entitled 'Metrology for Complex Components in High Value Manufacturing'.

#### • 13 May 2015 – Management of Asbestos in the Land, Durham

This is the sixth in a series of events jointly organised with SGS-MIS.

- 2 June 2015 Medical Laboratory Accreditation Workshop, Birmingham
- 14-15 July 2015 Annual Dinner, AGM, Seminar and Site Visit, Teddington

The BMTA Annual Dinner will be held at the Park Hotel, Teddington, on 14 July. The AGM will be followed by a Teddington Campus Showcase event featuring the work of NPL, NMO and LGC and including laboratory tours.

#### • Early October 2015 – Technical Competency Event, Manchester

Speakers at this event will examine training and qualifications needs for metrologists and laboratory staff. Topics will include methods of securing funding and training and apprenticeship products and supply. Discussions will include coverage of the Metrology Apprenticeship Trailblazer Group currently being promoted by NPL

- 15 October 2015 GTMA Make Measurement Matter Exhibition, Kettering
- 4-5 November 2015 Lab Innovations Exhibition, NEC, Birmingham
- 4-5 November 2015 Advanced Engineering Exhibition, NEC, Birmingham

In conjunction with these two important exhibitions, BMTA will run a Metrology Workshop at the NEC on 5 November. After initial presentations on developments at UKAS, BMTA and EUROLAB, the delegates will be divided into two workshops broadly covering (a) Dimensional Metrology and Advanced Engineering and (b) Laboratory-based Topics. Speakers from UKAS and other organisations will lead sessions on measurement uncertainty, traceability and verification and validation.

Please contact <a href="mailto:enquiries@bmta.co.uk">enquiries@bmta.co.uk</a> for more information or to express an interest in any of the above. Further information will be made available at <a href="http://www.bmta.co.uk/news.htm">http://www.bmta.co.uk/news.htm</a>

## **BULLAB** News

BULLAB has announced the signature of a *Memorandum for cooperation with the EA Bulgarian Accreditation Service (EA BAS)*. The Memorandum was signed by the Executive Director of EA BAS, Eng. Krastyu Ruynekov, BULLAB President Dr. George Todorov and BULLAB Organizational Secretary Eng. Alexander Petrov.

BULLAB has announced the publication of a research report on 'Means and approaches for solving problems in Conformity Assessment (CA) of industrial products in the EEA'. The authors (Prof. D.t.s. Branimir Sandalski and Mag.eng. Borislav Georgiev), have developed this research report as a response to the European Commission Communication "COM (2014) 25 final of 22.01.2014: A vision for the internal market for industrial products".

## National Members' News

## Fenelab News



Within Fenelab (the Association of Dutch laboratories, inspection and calibration organizations) many committees are constituted of active members who contribute to the association's success. During the last annual meeting this became apparent through the updates that were presented by these committees to the assembly.

Fenelab holds four policy committees that deal with issues in specific sectors, such as: Environment, Food, Construction and Electrical. Part of the Environment Policy Committee is a specialized – and very active - Technical Committee on Asbestos. In addition to the four policy committees, there are five committees that discuss issues that are important to all accredited laboratories, regardless of their sector. These are: Accreditation, Health & Safety Catalogue, Corporate Social Responsibility (CSR), Education & Labor and PR.

Going into detail would take up too much of this Newsbriefing. Therefore, a selection of issues that are currently being addressed within Fenelab are:

- · rapid analysis
- correct sampling
- Directive 210 CROW
- several validation studies (PAH Marker and TLC)
- · regular proficiency tests
- European vs. Dutch Regulation
- Construction Product Regulation (CPR)
- new and stricter limits on the types of chrysotile and amphibole asbestos types
- Electromagnetic Compatibility (EMC)
- Product safety
- · calibration
- L –scope
- Lab Experience Days
- adding new chapters to the Health & Safety Catalogue
- educational development for the laboratory sector

Fenelab as a whole, but also on the level of its committees, is an active advocate and representative of the accredited laboratory sector.

## **EUROLAB-CZ** News



EUROLAB-CZ: The Association of Accredited and Authorized Organizations (majority of members are Notified Bodies), member association of EUROLAB-CZ, and the Czech Chamber of Commerce signed on 20 February 2015 an Agreement on Cooperation to support the use of third party assessment and certification including education of entrepreneurs.

The training should be organized by the Chamber's regional units, to deepen the knowledge of entrepreneurs on the actual legislation and performance requirements laid down for their products, as well as about mandatory procedures concerning testing, inspection and certification.

## National Members' News

## MAKLAB News



# MACEDONIAN ASSOCIATION OF LABORATORIES AND INSPECTION BODIES



Following the working program, the Macedonian Association of laboratories and inspection bodies MAKLAB held the Annual assembly for 2015 on 25<sup>th</sup> of February. During the assembly the president of MAKLAB, MSc. Magdalena Trajkovska Trpevska has presented the annual report for undertaken activities in 2014 and the working program for 2015. The assembly has discussed the objectives of MAKLAB for the following period.

Organization of the International Conference "Quality and competence 2015" in September 2015 was pointed out as the most important activity for 2015. All relevant information for the Conference including the announcement for abstract and papers submission will be available soon online at www.maklab.org.mk.

MAKLAB is looking forward to welcome Eurolab members at the conference.







## TURKLAB News

TURKLAB contributed to the workshop for the Strategic Plan for Emergency and Disasters Management Turkish Legislation (TAYSB) 28<sup>th</sup> January 2015

Ms. Nese Gunes Board Member of TURKLAB and Mr. Mehmet Yakut, Member of TURKLAB participated in the workshop as panel speakers.

Vice-Prime Minister of Turkish Republic , Prof. Dr. Numan Kurtulmuş presented the opening speech. He declared that the government will strictly follow the decisions and results of this meeting. President of AFAD, Dr. Fuat Oktay announced that all institutions will be ready to operate at the initial moment of any disaster. Nese Gunes presented the importance of the conformity assessment for the strategic paper of Emergency and Disasters Management for Turkish legislation.

"ISO 22300 on terminology and ISO 22301 on BCM requirements were published in

2012 and adopted by CEN (the European Standardization Organization) as European standards. The decision was taken through CEN/TC 391, the European Committee on Social and Citizen Security. The adaptation of ISO standards by CEN will extend to encompass other safety and related fields. Especially in the field of schemes such as safety and emergency response, new legislation may come into force upon the acceptance of the recent standards and public authorities may wish to enforce this new legislation, standards and schemes.

Conformity Assessment Bodies will be able to take a vital role in checking the compliance or non-compliance according to the scheme imposed by the government. This adoption may eliminate the need for extra public surveillance activities and consequently will create new market opportunities for the TIC sector.



## TURKLAB News



## UILI LABMEETING, October 16-17, 2014, Izmir, TURKEY

International Laboratories Association UILI hold their annual international meeting in İzmir, Turkey. TURKLAB President, Dr. Ömer Güzel, was invited to present information about the Turkish Laboratory community. President of UILI, Dr. Menahem Fernandes made the opening speech. Dr. Ömer GÜZEL's presentation was entitled "Global Market, Global Accreditation and Global Performance of Laboratories.



## TURKLAB "Food Committee" meeting, October 13, 2014

13th October 2014, TURKLAB Food Committee meeting was performed by 41 participants. Main topic of the meeting was GMO testing and Method Unification for Ministry of Food & Agriculture specimens Technical Managers of laboratories organized sub committees to work for method unification and validation.





# TURKLAB participated in "The National Building Regulations Platform" established by The Association of Turkish Construction Materials Producers for the conformity assessment- January, 2015

The Association of Turkish Construction Materials Producers, an umbrella organization representing 29 industry associations and 80 industry companies and operating since 1984, started a project (an organization) to establish "the National Building Regulations Platform" for all stakeholders. The aim of this project is the collaboration of all stakeholders using a common platform to have sustainable buildings in terms of econo-

my, environment and safety. TURKLAB has joined this platform to contribute to **the conformity assessment** part of this umbrella project. An institute or an organization will be established with the participation of the nongovernmental organizations or similar bodies and companies. This institute or organization aims to cooperate with the public organizations and prepare the National Building Regulation.

#### TURKLAB Academy has been established.

TURKLAB established TURKLAB Academy for organizing training programs for members and also to all the private and public CAB's. These programs will include technical trainings, market surveillance trainings and auditor trainings according to the accreditation standards (ISO/IEC 17000 series). Programs will be conducted by the competent and expert trainers

who are experienced in the implementation of the standards and are knowledgeable in the national and international developments. TURKLAB Academy has already started to operate effectively. The organizational objectives of TURKLAB Academy are as follows:



- To improve the capabilities of its members considering new improvements in the conformity assessment activities,
- To ensure standardization in the practices in the accreditation inspections,
- To improve the capabilities of the accreditation bodies,
- To improve the capabilities of the authorized bodies for market surveillance activities,
- To improve the capacities of the laboratory infrastructure of the universities, industrial companies and public organizations in order to employ these laboratories in the conformity assessment and market surveillance activities and consequently to reinforce and improve the quality infrastructure of Turkey,
- To meet the training needs of its members economically and efficiently.

TS EN ISO /IEC 17065:2012 Training of Conformity assessment -- Requirements for bodies certifying products, processes and services - January 9-10, 2015.

## Accreditation

- IAF Executive Committee (EC) has submitted the revised IAF Policy Document titled: IAF Policy Document Memorandum of Understanding (Issue 5) for 30-day ballot to all IAF Voting Members.
   The IAF Memorandum of Understanding (MoU) is the basic membership document of IAF.
- Following the IAF 28th General Assembly meeting in Vancouver in October 2014, a communication has been distributed among members.
- Final Minutes for the ILAC-IAF Joint Development Support Committee (JDSC) meeting held on Tuesday 14 October 2014 in Vancouver, Canada have been distributed among the members.
- Agenda and documents for the upcoming IAF Technical Committee meeting, which will take place on 11 and 12 April in Frankfurt has been distributed among the members.
- Draft Final Minutes of the Vancouver General Assembly Meeting has been distributed among the members.
- A survey has been developed by the TC Task Force Principles for Determining Duration of AB Assessments. The TF has requested a reply to their survey by March 30, 2015.
- The following documents have been published on the IAF website: Issue 2, Version 1 of the IAF Quality Manual (This last version includes the new IAF Mission and Vision statements approved as part of the IAF Strategic Plan); IAF Public Document Responsibility list; the IAF Representatives, Liaisons and Contacts list.
- The results of the 30-Day Ballot IAF Informative Document - Information on the Transition of Management Systems Accreditation to ISO/IEC 17021-1:2015 from ISO/IEC 17021:2011 has been published. Members voted in favour of the revision.
- The following draft documents have been circulated by ILAC for comments: JCGM 100:201X Evaluation of Measurement Data-Guide to Uncertainty in Measurement (GUM2); JCGM 110:201X Evaluation of Measurement Data-Examples of Uncertainty Evaluation.
- The EA-1/17 Rules of Procedure have been revised. The objective was to introduce the position of the EA Executive Secretary and the subsequent changes in EA's structure.
- The results of the 30-Day IAF Ballot on New Joint IAF/ILAC Document: Approval Process for IAF/ ILAC A-Series Documents has been published. Members voted in favour of the revision.
- The following documents have been published on the IAF website: Joint IAF-ILAC-ISO Communiqué on the Management system requirements of ISO 15189:2012 Medical laboratories Particular requirements for quality and competence; The joint IAF-ILAC-ISO communiqué on ISO 15189 accreditation has been updated to reflect the transition from ISO 15189:2007 to ISO 15189:2012; Press Release ISO, ILAC and IAF streamline quality

- management requirements for medical laboratories.
- IAF members will vote for a new IAF Vice-Chair.
- Meeting documents for the next IAF Technical Committee meeting which will take place Saturday and Sunday April 11-12, 2015 have been distributed among the members.
  - ILAC Marketing and Communications Committee (MCC) has submitted the following document titled: "ILAC-R4:Draft February 2015 Use of the ILAC Logo and Tagline" to ILAC Members for a 30-day voting period.
  - IAF TC Chair has submitted the following documents for comments: IAF MDX Generic Competence for AB Assessors: Application to ISO/IEC 17011 and the draft document Expected Outcomes Document -ISO 22000 Food. The objective of the first document is to ensure the consistent and harmonized application of ISO/IEC 17011 for defining the generic competence for assessors while the scope of the second one is to be a joint communique between IAF and ISO.
  - Nominations for the Position of IAF Technical Committee Chair (2016-2019) and Nomination(s) for the Position of IAF MLA Committee Chair (2016-2019) have been opened. The first term of the current IAF Technical Committee Chair (Mr. Ekanit Romyanon) and the second term of the current IAF MLA Committee Chair (Mr. Steve Keeling) will end following the conclusion of the Joint Annual Meetings of IAF and ILAC to be held in Milan on 28 October 6 November, 2015. Mr. Ekanit Romyanon has confirmed that he is willing to stand for a second term as Chair of the IAF Technical Committee while Mr. Keeling has served two full terms thus a new Chair must now be selected.
  - The Draft Minutes of the Eighteenth ILAC General Assembly which took place in Vancouver, Canada, October 2014 have been circulated among members.
  - The results of the Ballot related to the **Draft IAF MD** 5: 201X Determination of Audit Time of Quality and Environmental Management Systems (Issue 3) have been circulated among members.
  - After the comments and ballot period, the Issue 1 of IAF MD 17: Witnessing Activities for the Accreditation of Management Systems Certification Bodies has been published on the IAF website (iaf.nu), under Publications, Mandatory Documents.
  - The IAF TC Working Group (WG) on ISMS has developed a survey on issues arising from the **revision of ISO/IEC 27001** and issues arising from the **implementation of ISO/IEC 27006**.
  - Issue 2 of IAF MD 8: Application of ISO/IEC 17011:2004 in the Field of Medical Device Quality Management Systems (ISO 13485) and Issue 2 of IAF MD 9: Application of ISO/IEC 17021 in the Field of Medical Device Quality Management Systems (ISO 13485) have been published and are now available on the IAF website (iaf.nu), under Publi-

No I

- cations, Mandatory Documents.
- An editorial change was made to the Issue 1 of the MD17 document on Witnessing Activities for the Accreditation of Management Systems Certification Bodies on page 15, in Section 5, in the table i.e. a line to separate the Construction and Goods Production technical clusters was missing, and has been added.
- Issue 1 of IAF MD 18: Application of ISO/IEC 17021:2011 in the Service Management Sector (ISO/IEC 20000-1) has been published and it is available on the IAF website (iaf.nu), under Publications, Mandatory Documents.
- The IAF Technical Committee (TC) has submitted the new IAF Informative Document titled: Transition Planning Guidance for ISO 14001:2015 to all IAF Voting Members for a 30-day voting period. The Draft IAF Informative Document provides guidance for the transition from ISO 14001:2004 to ISO 14001:2015.
- The IAF and ILAC Executive Committees have submitted the new IAF-ILAC Joint Publications (A-Series) document titled "IAF/ILAC-A6:XX/201X - Approval Process for IAF/ILAC A-Series Documents" for a 30-day voting period. IAF and ILAC are conducting this ballot in parallel.
- A new draft document titled EA-2/XX M "EA Document on the Confirmation of the Continuation of Accreditation based on the Results of Surveillance Activities" has been circulated for comments among the members.
- The results of the Second 30-Day Ballot IAF Informative Document Transition Planning Guidance for ISO 9001:2015 have been circulated among members.

## **Standardisation**

- Voting results and comments on the ISO/TS 22002-3: Prerequisite programmes on food safety -- Part 3: Farming have been distributed among members.
- Conformity assessment queries in CEN/CLC standards have been recently published on the members area
  of CEN website.
- The new ISO Action Plan for developing countries 2011-2015 has been distributed among members. In order to
  enhance developing country participation in ISO technical work, they will now be entitled to three sponsorships per
  calendar year to attend technical committee meetings of their choice, funded by ISO.
- The following documents have been published on the ISO/TC 34/SC 17 eCommittee:
- ⇒ SC17 N371 ISO TC234 "Management systems for food safety" N 213 and N218 Resolutions and Report from meeting in Trondheim 2014-11-19
- ⇒ SC17 N372 ISO TC034 "Management systems for food safety" N1760 Codex CCFH hygiene Report meeting November 2014
- ⇒ Justification Study for the revision of ISO 22000, Food safety management systems Requirements for any organization in the food chain
- The ballot related to ISO/IEC 17043:2010 Conformity assessment General requirements for proficiency testing has opened.
- CEN and CENELEC are drafting a Guide on Standards and Regulation. The Guide is aimed primarily at public authority policy makers and elected representatives, and offers an introduction to explain the view of the European standardization communities of CEN and CENELEC taking into consideration the ISO/IEC Guide on Standards and Regulation, ensuring coherence on the matter with the international views.

## **Business** news

- Bureau Veritas has finalized the acquisition of a 70% equity stake in Ningbo Hengxin Engineering Testing
  Co., Ltd ("Ningbo Hengxin"), a Chinese company specialized in non-destructive inspection and metallurgical
  testing.
- Bureau Veritas has announced the acquisition of CTS, a Chinese laboratory specializing in the testing of toys, electrical goods, electronics and hardlines.
- Bureau Veritas has announced the expansion of its product testing laboratory in Pakistan. The expanded laboratory serves as a key testing facility for the textile and garment industry in Pakistan as well as an enhancement to the Bureau Veritas laboratories network throughout South Asia region.
- Bureau Veritas Consumer Products Services (BVCPS) has announced the opening of its new Guangzhou
  laboratory specializing in the testing and certification of large domestic appliances, HVAC/R and automotive components and systems.
- Bureau Veritas Vietnam has added new food test capability to its portfolio in 2015 with plans for almost 100 additional tests to become accredited by VILAS, the Vietnam Laboratory Accreditation Scheme, in Q1 2015.

- The Consumer Technology Division of UL has extended its agreements with Anritsu, a testing and measurements equipment manufacturer, as the provider for Long Term Evolution Advanced (LTE-A) telecoms test equipment, becoming the first commercial independent LTE-Advanced 3 Carrier Aggregation conformance test facility in the world.
- The Cologne Solar Energy Assessment Center of TÜV Rheinland has received recognition by the Swiss Cantonal Fire Insurance Association VKF for the execution of hail tests according to various test methods. The TÜV Rheinland experts can now test building elements for roofs, facades as well as windows, shutters, photovoltaic modules and solar thermal collectors according to the required hail resistance classes 3 to 5.
- DEKRA is expanding its product testing business in Asia. The organisation has signed an agreement for acquisition of the QuieTek Corporation in Taipei, Taiwan. This purchase complements DE-KRA's service portfolio and strengthens DEKRA's position in testing of electrical and electronic products and components.
- DEKRA is warning against highly flammable Carnival articles. Tests have shown that some masks and wigs can easily catch fire, burn for a long time and injure jesters and revellers all because of a legal grey zone. In the run-up to the Nuremberg International Toy Fair, DEKRA conducted its own market research by anonymously testing a range of Carnival masks and wigs (zombies, pirates, skulls, devils and monkeys) purchased online.
- DNV GL will develop a study to assess electricity end-use efficiency which will enable the forecast of future electricity consumption trends and the development of appropriate planning methodologies.
- DNV GL has stated that 30% of components tested in its laboratories fail to pass the physical • laboratory tests and don't achieve certification. Independent certification of power system components helps ensure that utilities provide the most reliable service possible.
- FORCE Technology has announced that its newly constructed high-pressure calibration facility will officially open its doors to visitors on 13 May 2015.
- Korea Institute of Lighting Technology (KILT) has been appointed as DEKRA's CB Testing Laboratory (CBTL) under IECEE CB Scheme. KILT has been a partner of DEKRA since February 2013, and now DEKRA's LED Lighting customers in Korea can get DEKRA's certificates and other international approvals based on local testing at KILT.
- Intertek has inaugurated a comprehensive leather and footwear testing facility in Bangladesh to support the leather, footwear and leather

- goods industries in South Asia.
- Intertek has expanded investments in new capabilities and capacity in North America to enhance its industry services in support of the refrigeration industry. With total investments of more than \$20 million over the past 3 years, Intertek offers laboratory testing services providing a source for manufacturers bringing new products to market.
- Intertek has confirmed its commitment to the Humberside oil and gas industry with the opening of a new, state-of-the-art 300m<sup>2</sup> petroleum testing and inspection laboratory in Immingham Docks.
- Intertek has inaugurated the first-ever dedicated footwear lab in Bangladesh that is accredited per ISO / IEC 17025:2005. To further support South Asia's leather, footwear and leathergoods industry, Intertek has entered into a synergistic agreement with Leathergoods & Footwear Manufacturers & Exporters Association of Bangladesh (LFMEAB) for mutual business support and development leveraging the expertise and networks of both the organizations.
- Intertek has announced the opening of a brand new laboratory located in Hooton, in the north west of England. Previously located Capenhurst, Intertek Clinical Research Services (CRS) has more than doubled the size of its Laboratory. The Hooton facility also incorporates the main administrative office for Intertek CRS, providing management of the services offered in oral care, dermatology, nutrition and healthcare research. Intertek has been awarded the ISO / IEC 17025 accreditation for its Precision Agriculture Laboratory based in Johannesburg, South Africa. The accreditation comprises chemical and microbiological analyses to ISO/IEC 1725:2005. These analyses
  - Intertek has signed a contract with the Ghana Standard Authority (GSA) to provide verification and testing services to exporters worldwide, delivering Certificates of Conformity (CoC) for regulated goods meeting Ghana's import standards.

are performed on Soil, Fertilizer, Water, Feed, and

Food by this purpose-built laboratory.

- Intertek is providing transformer oil quality testing in Singapore, under the global TransoilCHECK™ program. TransoilCHECK™ is a preventive oil condition based maintenance program providing owners and operators with quality testing results and condition trend-monitoring information.
- Intertek has invested £1.2m expanding its centre of excellence for corrosion testing services to meet growing demand for asset life extension solutions in the oil and gas industry. The expansion, which has been driven by major new contract awards worth around £1m, takes the total investment in the Manchester, UK, site to over £5m

- since it first opened in 2008.
- Intertek has inaugurated a comprehensive leather and footwear testing facility in Bangladesh to support the leather, footwear and leather goods industries in South Asia.
- Intertek (LSE: ITRK) has expanded investments in new capabilities and capacity in North America to enhance its industry services in support of the refrigeration industry. With total investments of more than \$20 million over the past 3 years, Intertek offers
   laboratory testing services providing a source for manufacturers bringing new products to market.
- Intertek has announced its investment in expanded facilities and new testing devices to enhance its industry services in support of building products manufacturers. With these expanded capabilities, Intertek offers customers access to both experts and testing solutions, as well as international markets.
- SGS has announced the acquisition of AirServices
  Estudos e Avaliações Ambientais Ltda., in Sao
  Paulo and Cronolab Referência em Análises Químicas
  e Ambientais Ltda., in Rio de Janeiro. AirServices performs air emission monitoring and testing, as well as
  environmental studies, while Cronolab provides water,
  soil and air testing, with a special focus on dioxins and
  furans
- SGS Life Science Services has announced the completion of an investment at its facility in West Chester, PA. Multiple new instruments for advanced analytical techniques have been installed and validated to support clients in the structural analysis of proteins.
- SGS Life Science Services has announced that its laboratory in Poitiers, France, has completed a full analytical validation of the novel Meso Scale Discovery (MSD®) V-PLEX 10-plex Proinflammatory Panel I, for use with human plasma samples. The validation included measurement of accuracy, recovery, dilutional linearity, and stability, using a set of inhouse, as well as the manufacturer's surrogate validation quality controls.
- SGS in Indonesia has announced the opening of its new Footwear Physical Laboratory in Jakarta, Cilandak. This new testing facility builds on the country's successful footwear testing services, offered since 2011.
- Spirent Communications, a company specialized in networks, services and devices testing, has announced that it had signed a co-operation agreement with TÜV NORD GROUP to jointly develop testing services for Ethernet-based networks in vehicles. The focus will be on defining comprehensive test scenarios that ensure the data networks in vehicles meet the highest requirements when it comes to reliability and safety.
- A joint laboratory between the Centro Protesi Inail and the Campus Bio-Medico of Rome, in the province of Bologna has opened. The purpose is the

development of a project at the forefront of the prosthetic upper limb.

- TÜV SÜD is reinforcing its focus on food safety. On 1 January 2015 Dr Ron Wacker took over international responsibility for the new Food, Health & Beauty Business Unit of TÜV SÜD Product Service Division. This business unit combines TÜV SÜD's complete range of services throughout the supply chain, such as laboratory analyses, certifications, inspections and audits.
- TÜV SÜD has inaugurated a state-of-the-art leather and leather product testing laboratory at Ranipet in the Indian state of Tamil Nadu. The new laboratory offers a complete gamut of services ranging from REACH, ROHS, analytical and physical services to mechanical services for leather and footwear products.
- VdTÜV published its position paper on Transatlantic Trade and Investment Partnership (TTIP). For details follow the link: http:// www.vdtuev.de/news/vdtuev-veroeffentlichtposition-zu-ttip
  - UL Consumer Technology has announced the launch of a comprehensive service that offers customized product validation, advisory, testing, risk mitigation, interoperability, and global market access services for wearable technology products.
- UL has announced that its testing laboratory in Taiwan has been appointed by Taiwan's Bureau of Standards, Metrology and Inspection (BSMI) as the designated test laboratory for small appliances.
- A joint laboratory between the Institute and the Campus Bio-Medico of Rome at the Centre for Prosthetics INAIL, in the province of Bologna has opened. The purpose is the development of a project at the forefront of the prosthetic upper limb.
  - SGS has announced that its laboratory in Ankara, Turkey has been recognized by the International Accreditation Service (IAS) for meeting the requirements of the ISO/IEC 17025 standard for specific registered tests for the minerals industry. Conformance to ISO/IEC 17025 demonstrates technical competency for a defined scope of tests and the operation of a laboratory quality management system.
  - SGS has announced the opening of a new Footwear Laboratory at SGS Gunesli, Istanbul. The Turkey lab can provide a range of physical and chemical testing services for footwear, textiles, leather, hardgoods, cosmetics and toys and juvinile products.
  - SGS Life Science Services, has announced that it has invested in X-Ray Powder Diffraction (XRPD) capabilities at its Lincolnshire, IL, laboratory for solid state analysis. The service can now be offered to clients wishing to study crystallinity and polymorphism under cGMP conditions.

## **Business Results**

## **Bureau Veritas** (report)

- Revenue of EUR 4.17 billion, +9.4% at constant currencies.
- •Organic growth of 2.5% with an improvement in Q4 (+3.4%)
- External growth of 6.9% driven by 8 acquisitions in strategic markets

## **Intertek (report)**

- Constant currency revenue up 2.3%, including acquisitions which added 2.9%.
- Constant currency organic revenue down 0.6%; and up 1.4% excluding low-value Industry contract exits.
- •Operating margin1 15.5%, down 20bps.

## SGS

- Revenue of CHF 5.9 billion, up 5.4%
- Adjusted operating income of CHF 947 million, up 2.6%
- Adjusted operating margin of 16.1%
- Free cash flow of 607 million, up 2.7%
- EBIT margin of 16.0%, up 0.6%
- Basic earnings per share of CHF 81.99, up 10.9%
- Proposed dividend of CHF 68, up 4.6%

## **Policy news**

## **Chemicals**

- ECHA has published its 2014 CMR Report. The report shows that companies are adhering well to the harmonised classification of substances which have carcinogenic, mutagenic or reprotoxic properties (CMRs). It also identifies over a thousand CMR substances that potentially merit further regulatory action such as harmonised classification and, where relevant, identification as Substance of Very High Concern. http://tinyurl.com/owscf34
- ECHA has published its REACH 2018 Roadmap, which outlines the Agency's milestones planned in the run up towards the final REACH registration deadline. The last registration deadline for existing chemicals will be on 31 May 2018. The deadline concerns companies that manufacture or import substances in low volumes, between 1-100 tonnes per year. http://tinyurl.com/o5arh2y
- The European Commission and its non-food 
   Scientific Committee on Health and Environmental Risks (SCHER) have published their final Opinion assessing the safety levels of chromium VI in toys. A new science fact sheet on this topic is also available.
- ECHA has published the annual REACH Evaluation Report 2014. The report shows that a considerable share of the examined registration dossiers still requires improvement. At the same time, more registrants comply with ECHA's dossier evaluation decisions.
- The REACH annexes VIII, IX and X have been amended with the inclusion of the extended onegeneration reproductive toxicity study (EOGRTS, EU B.56, OECD TG 443). EOGRTS will now be the

- The European Commission has published its response to concerned citizens about the use of animal testing for cosmetics ingredients under the REACH Regulation. The public campaign was initiated by the People for the Ethical Treatment of Animals UK (PETA). http://tinyurl.com/p3g6eyl
- During its ninth plenary meeting the Biocidal Products Committee (BPC) has adopted 13 opinions. These opinions cover five active substances in 10 product types. <a href="http://tinyurl.com/ovfjemp">http://tinyurl.com/ovfjemp</a>
- ECHA has clarified how to report substances used in hydraulic fracturing. Companies can now report more explicitly to ECHA in the current IUCLID the use of substances in the exploration or extraction of oil and gas using hydraulic fracturing techniques. <a href="http://tinyurl.com/pmb4ayd">http://tinyurl.com/pmb4ayd</a>
- The Committee for Risk Assessment has examined 12 applications for authorisation on 17 uses of trichloroethylene and consequently has agreed on 11 draft opinions and adopted one restriction proposal on ammonium salts in cellulose insulation materials. It has also adopted six opinions for harmonised classification and labelling. http://tinyurl.com/o585cww
- ECHA has adopted the final Community rolling action plan (CoRAP) for 2015-2017. Member States will carry out substance evaluation in the coming three years for 66 newly selected substances and 68 substances from the previous CoRAP update. They will have to evaluate 48 substances over the next 12 months.

## **Consumer Protection**

• The Italian Presidency has provided the Competitiveness Council with information on the state of play regarding the proposal for a Regulation on consumer product safety (CPSR). At the request of Member States the Presidency, with the aim of overcoming the present deadlock over Article 7, has invited the EC to present further evidence on the costs and benefits of the mandatory marking of origin for businesses, authorities and consumers. The EC has announced that it was currently gathering further

information and evidence through a technical study to be presented in early 2015.

On 23 March 2015, the European Commission published the 2014 Rapex Report, showing that in 2014, nearly 2500 products, ranging from toys to motor vehicles, were either stopped before they entered the EU or removed from markets because they were dangerous for EU consumers. The new 2014 RAPEX Annual Report, contains information on notifying and reacting countries, countries of origin and types of products subject to notification, risks posed and measures taken in 2014.

## **Environment**

- Buildings Performance Institute Europe has published a report entitled <u>'Energy Performance Certificates across the EU'</u>. This detailed country-by-country overview of qualification and accreditation requirements of building energy certifiers demonstrates the diversity of approaches across Europe. It is of critical importance to include in all Member States' legislation minimum standards for training and experience as well as the need for independent accreditation procedures.
- The European Parliament has failed to pass a joint resolution against the Commission's intention to withdraw the pending EU laws on waste and recycling, known as the Circular Economy package. Each political group has tabled its own resolution. Although none of the separate resolutions has received a majority when voted on, all of them have backed calls for EU proposals on air quality and recycling not be withdrawn as part of the Commission's 2015 Work Programme. <a href="http://tinyurl.com/nlfoote">http://tinyurl.com/nlfoote</a>
- The European Commission has adopted its <u>strategy for a European Energy Union</u>. By unveiling its strategy to achieve a resilient Energy Union with a forward-looking climate change policy, the European Commission delivers on a top priority set out in President Juncker's political guidelines. <a href="http://tinyurl.com/ljrwyxz">http://tinyurl.com/ljrwyxz</a>
- The ENVI Committee has approved a draft law that caps the production of traditional biofuels and accelerates
  the shift to alternative sources, such as seaweed and waste. It aims to reduce greenhouse gas emissions that
  result from the growing use of agricultural land to produce biofuel crops. <a href="http://tinyurl.com/kjce3ku">http://tinyurl.com/kjce3ku</a>
- The Energy Efficiency Financial Institutions Group (EEFIG), an expert group set-up by the European Commission and United Nations Environment Programme Finance Initiative has published a <a href="new report">new report</a> entitled 'Energy Efficiency the first fuel for the EU Economy. How to drive new finance for energy efficiency investments'.
- The EU leaders has set out the first steps of an Energy Union. The European Council strengthened has their commitment for affordable, secure and sustainable energy within the EU. Read the European Council Conclusions on the Energy Union.

## **FOOD**

- The European Food Safety Authority (EFSA) has published its <u>Single Programming Document for 2015-2017</u>, which describes the EFSA scientific, communication and corporate activities during the next three years.
- The members of the ENVI Committee have passed a resolution urging the Commission to table new legislation, obliging firms to put country-of-origin information on processed meat. The resolution is to be discussed along with an oral question to the Commission, and put to a plenary session vote in February. <a href="http://tinyurl.com/lkv4k3">http://tinyurl.com/lkv4k3</a>
- The European Commission has welcomed the United States Department of Agriculture's (USDA) announcement that the US will progressively re-open its market to exports of beef from the European Union from January 2015, starting with the Republic of Ireland. The US market has been closed to any EU beef since January 1998. <a href="https://tinyurl.com/pxm8n6z">https://tinyurl.com/pxm8n6z</a>
- During the EP Plenary Session in February in Strasbourg, the MEPs adopted by 460 votes to 204, with 33 abstentions, a resolution tabled by the ENVI Com-

- mittee, on country of origin labelling for meat in processed food. The Commission is called upon to follow up its 2013 report with legislative proposals making this indication mandatory.
- The European Food Safety Authority (EFSA) has launched its scientific data warehouse project, which will allow the publication, analysis and distribution, in different formats and at different levels of granularity, of data collected by EFSA. Gradually, over the course of 2015, different stakeholders will be granted access. <a href="https://tinyurl.com/kvamnxc">https://tinyurl.com/kvamnxc</a>
- The European Food Safety Authority (EFSA) has published its latest EU Summary Report on antimicrobial resistance in zoonotic and indicator bacteria from humans, animals and food in 2013. According to the report treatment options for some of the most common food-borne infections are decreasing, as types of bacteria (called 'isolates') continue to show resistance to antimicrobial drugs.

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- The European Food Safety Authority (EFSA) has published a Scientific Opinion addressing the state of the science on risk assessment of plant protection products for non-target arthropods. The document explains the science that will support the development of a full risk assessment scheme and is based on a review of the current scheme
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- Draft Assessment Reports, Renewal Assessment Reports and sanitisation (i.e. redaction) of background documents for the EU peer review of active substances are already shared electronically among EFSA and its stakeholders. Applicants can use their own user name and password to access an online platform for sharing these documents with EFSA. <a href="https://tinyurl.com/p697hsq">https://tinyurl.com/p697hsq</a>

## **Medical Devices**

- At the request of the Dutch Health Care Inspectorate, The National Institute for Public Health and the Environment (RIVM) has compared the market authorization systems for medical devices in the USA and Europe. Based on the comparison of the requirements of both systems, it cannot be concluded that one or the other system leads to safer medical devices on the market. <a href="http://tinyurl.com/n89mfx9">http://tinyurl.com/n89mfx9</a>
- The proposal on medical devices has been examined in the Council at Working Party level. http://tinyurl.com/ owbslgz
- The European Commission has published a new fact sheet on the safety of Metal-on-Metal hip implants
- The 2 draft regulations on medical devices and in vitro diagnostic medical devices have been examined in the Council at Working Party level. <a href="http://tinyurl.com/keqksqg">http://tinyurl.com/keqksqg</a>
- Ken Research has released a new report which looks into Germany's medical device market overview 2013 to 2018. It provides statistics on market size of region and countries covered, market segmentation by medical device equipments, export and import statistics by country, industry trends, Mergers and acquisitions. <a href="http://tinyurl.com/l7z99xm">http://tinyurl.com/l7z99xm</a>

## Transatlantic Trade and Investment Partnership (TTIP)

- The members of the INTA Committee have discussed the <u>draft report by INTA Chairman Bernd Lange</u> containing the EP's recommendations to the Commission on TTIP. 10 out of the 13 parliamentary committees that will contribute to the report have also discussed or voted on their draft opinions. <a href="https://tinyurl.com/n64ysow">https://tinyurl.com/n64ysow</a>
- IMCO and INTA Committee have held a Joint Public Hearing on TTIP. The first panel was chaired by the IMCO Chair Vicky Ford and focussed on standards and consumer protection standards. The second panel was chaired by the INTA Vice-Chair Tokia Saïfi and focussed on regulatory cooperation in the field of motor vehicles. http://tinyurl.com/luramw8
- The Directorate General for Trade of the European Commission has organised two stakeholder engagement events during the 8<sup>th</sup> Round TTIP Negotiations. http://tinyurl.com/ktfvuoy
- The members of the IMCO Committee have voted on its recommendations to the European Commission on the negotiations for the TTIP. The draft opinion of Rapporteur Dita Charanzová (ALDE) has been adopted with 20 votes in favour, 18 against and 1 abstention. The lead INTA Committee will vote on its report in May.
- The Centre for European Policy Studies (CEPS) has published a paper that reviews the current state of affairs between the US and the EU on government procurement, examining the procurement that they open to one another and the procurement that they withhold. http://tinyurl.com/nduqwpy

# Wilfried Hinrichs, EUROLAB-Germany, attended the 29th EA CC (Certification Committee) and EA IC (Inspection Committee) meetings, 3rd – 6th March 2015 in Bern, Switzerland

#### **Certification Committee**

An important part of the meeting was the so-called 'harmonization session' on questions and answers prepared by a Review Panel. Here are two examples addressing testing:

- It was asked whether it is possible to base certification on test results only. The answer was positive. ISO 17067 provide a certification system for that.
- It was asked whether a laboratory must be accredited according to ISO/IEC 17025 when the test results are used for certification according to system 2+ (conformity of factory production control on the basis of the CPR). The answer was that testing must be in accordance with ISO 17025, but the laboratory must not necessarily be accredited to this standard. The Certification Committee discussed its approach to the 'High Level Structure' elements in the future Conformity Assessment Standards. It was said that ISO created HLS due to a still growing number of management system standards which have slightly different structures and often different definitions for the same terms. The concept elements 'risk-based thinking' and increased leadership instead of management requirements were picked up in several discussions in the meeting. The CC is going to prepare a workshop on the Annex SL of ISO 9001:2015 (expected to be published in Sept. 2015) and the High Level Structure as this will have implications on the accreditation of certification bodies. The HLS was also the topic in a Strategic Discussion. The participant including the stakeholders agreed that these changes don't have a significant influence on the accreditation process but it seems to be a challenge to the accreditation bodies, especially to the assessors. Here are the main questions and answers in the framework of the discussion:
- How can a certification body demonstrate to an accreditation body its ability to assess the organisation's Risk Based Thinking?

  The accreditation body cannot require from a certification body to have carried out a risk-analysis on the basis of the standard as it is now. But the assessors must be aware of the risk-based thinking.
- How can a certification body demonstrate to an accreditation body how the organisational context is built in to audit programmes and activities? There will be questions about the organisational context in the course of future audits but it should be a broad area where concepts of procedures do not work so well. Audit plans must be more adapted to the certification body.
- At a witnessed assessment, what might the national accreditation body expect to see in order to identify that the certification body has understood and implemented the new requirements of the certification standard resulting from the HLS? Here no big changes are expected in witness assessments.

### **Inspection Committee**

The IC dedicated most of its meeting time to ILAC P15:06/2014 (Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies), as it is published and a valid document. It was said that EA has already given a signal to ILAC that P15 should be revised, especially chap. 8. According to this information ILAC is treating the matter. The IC wants an early revision in order to address the use of Option B with reference to 8.1.3.

A workshop on ISO 17020:2012 / ILAC P15 was a full day event with discussion and presentation of results in order to get the participant more familiar with the requirements and to highlight those things that are new and waiting for an answer. Sometimes it seemed that some requirements have been weakened by P15. A long discussion was on the required interval of internal audits (yearly or not -8.6.2 to 8.6.4). P15 defines this in another way but does it make not more clear. In this course - and apart from the impartiality - three categories of risks were identified: activities, relationships and personnel.

#### **Next meetings:**

CC: 6-7 Oct 2015; IC: 8 Oct. 2015in Lisbon (Portugal) Spring 2016: Vilnius (Lithuania)

## Report on the EA LC meeting, 18 – 19 March 2015 in Athens, Greece

This meeting of the EA Laboratory Committee (EA LC) was chaired by Natalija Jovic-Zaric from ATS, the Accreditation Body of Serbia. Laurent Vinson, COFRAC, was elected as vice-chairman. As stakeholder organisations Eurachem and EUROLAB were represented by Brian Brookman, Irache Visiers and Manfred Golze, respectively.

#### Opinions and interpretations (O+I)

Trevor Thompson, the convenor of the Task Force Group (TFG) on opinions and interpretations (O+I) in test reports concluded that no consensus could be reached on the following major aspects:

- Should O+I be a separate identifiable feature appearing on Certificates of Accreditation (schedule, scope, annexe etc.)?
- Should assessment of O+I be mandatory for ABs upon the request of laboratories?
- Should O+I be an accredited activity at all, or should it, when appearing on test reports, be disclaimed?

As the new draft guidance document was circulated so late, it was neither possible to consult with the own organisation nor even to read it before the EA LC meeting. Therefore it was decided that the EA members should vote on the following three options within 1 month time:

- A) Publish the attached document as "Informative", i.e. non-mandatory, but offered as a best practice guide
- B) Put the work on hold until after the publication of the revised 17025 in around 2018.
- C) Do nothing and leave AB practice as is.

As a stakeholder organisation EUROLAB cannot vote, but should comment on these options in time. The EA LC discussed the following topics in-depth:

#### Implementation of the work of the Technical Networks (TNs)

TNs were generally acknowledged as useful tools for discussion of technical questions among accreditation bodies (ABs). But the list of the members should regularly been reviewed and updated. It was suggested to include stakeholders in the TNs, but this would require changes in the general Terms of Reference (ToR) of the TNs. To facilitate the co-operation internet fora and video conferences were suggested. Each TN should have a clear scope and could compile lists of frequently asked questions (FAQs). At present no TN should be disbanded because the revision of ISO/IEC 17025 might raise new questions. The EA LC Management Group (EA LC MG) will prepare a proposal for the future work based on this discussion.

## Main topics to be discussed by the EA LC members

It was suggested to arrange more breakout sessions during the meetings in order to allow for more in-depth discussions of important issues. As a consequence it was decided to reserve the 2<sup>nd</sup> day of the coming meeting for breakout sessions. Summaries of the results should be produced.

#### Use of the results of EA highlighted ILCs in the Peer Evaluation

Anna Stefanidou, ESYD, pointed out that the results of the EA highlighted Interlaboratory Comparisons (ILCs) could only be used by the two EA LC ILC Working Groups to demonstrate the functioning of the EA Multilateral Agreement (MLA) if a sufficient coverage of the EA member countries could be achieved. She urged the EA members to nominate accredited laboratories of their countries for participation. A controversial discussion revealed that many ABs are still reluctant to nominate laboratories and to provide the necessary information. The EA LC re-confirmed a resolution of 2012 on a change of the document EA-2/02 EA policy and procedures for the multilateral agreement and set-up a TFG, convened by Laurent Vinson, that should prepare a position paper of the EA LC which should be submitted to the EA MAC (Multilateral Agreement Council).

#### Revision of the GUM

Maurice Cox, NPL, informed the EA LC members on the revision of the *Guide to the expression of uncertainty in measurement* (GUM) which resulted in a first draft. In December 2014 this draft was circulated for comments to the 8 international organisations which constitute the Joint Committee for Guides in Metrology (JCGM). A workshop will be organised by the International Bureau for Weights and Measures (BIPM) in Sèvres near Paris on 15 - 16 June 2015. A major change concerns the evaluation of input quantities from n repeated measurements (Type A). The new formula given for the connected uncertainty component requires at least n=4 measurements. Furthermore, for the calculation of coverage intervals (expanded uncertainties) the use of a coverage factor of k=2 for a coverage probability p=95% is deemed to be justified only if a normal distribution of the measurand can reasonably be assumed. If the distribution is unknown two additional cases (for p=95%) are specified:

- for a symmetric distribution: k = 3
- for an asymmetric distribution: k = 4.5.

#### **Open session for questions**

In the session for questions three questions had been submitted and were answered by EA LC members. Questions and answers will be compiled and published in the EA LC intranet (FAQ).

## Use of external persons in internal audits (EUROLAB)

EUROLAB asked whether EA members would require the use of an external person for internal audits in order to ensure the independence of the auditor when auditing the clauses of ISO/IEC 17025, in particular those of chapter 4. The answer was a clear "no", because the requirements concerning the independence of the auditor in clause 4.14.1 of ISO/IEC 17025 were qualified ("wherever resources permit").

## EA LC took the following decisions:

Rob Bettinson was appointed as the new convenor of the TFG on the establishment of an MLA for the accreditation of reference material producers and of PT providers.

A TFG was set up to elaborate a position paper on harmonisation in the field of pesticides residues analysis based on the results of a survey which had been performed among EA members.

The final draft of EA-4/19 on the scopes of accredited PT providers was endorsed and will be circulated for voting as guidance document. The final draft of the revised document EA-4/15 on Non-Destructive testing was endorsed and will be circulated for voting.

The revised final draft of EA-4/09 on accreditation for sensory testing laboratories will be circulated for comments.

The EA LC supported the adoption of ILAC G19 on modules in a forensic science process as an informative document by the EA Ge neral Assembly (EA GA) in November 2014.

The draft EA Work Plan 2016 was approved by the EA LC and will finally be decided by the EA GA in May 2015. Among others the co-operation with stakeholders was addressed, and some EA LC members discussed a revitalisation of the Permanent Liaison Group (PLG).

The EA LC was informed that:

- the two EA LC WG on ILCs in testing and calibration, respectively, had decided not to merge and would continue with two meetings per year,
- the revision of document ILAC G17 on measurement uncertainty in testing was put on hold because of the ongoing revisions of ISO/ IEC 17025 and of the GUM,
- ILAC G18 on scopes is under revision.

The next EA LC meetings will take place:

- in Belgrade on 9 10 September 2015,
- in Prague on 16 17 March 2016.

One topic which will be discussed during the coming meeting will be the assessment of compliance with national regulations

## Carol Steward, Exova and Peter Blinksbjerg, EUROLAB-Danmark attended the ISO/CASCO WG 44. Revision of ISO/IEC 17025, February 10th to 12th, 2015 in Geneva, Switzerland

The meeting was opened by the convener Warren Merkel, and the agenda was accepted as it was distributed.

Sean Mac Curtain introduced the ISO system. At the end of the introduction, a decision was taken on the speed of finalization of the standard. The default track was proposed (24 months to DIS) – and agreed by consensus. (The first decision made using Merkel's "Thumps up" approach). This decision entails that the Work plan distributed before the meeting stands.

EUROLAB raised the question why "Conformity assessment" was added to the title of the revised standard. Both that wording and "General" in the title of the new standard can be discussed at a later stage.

Sean Mac Curtain highlighted, that everybody participate in WG 44 as nominated experts, and they should react as such. This means that normally there will not be scheduled time consulting in e.g. national mirror groups.

#### Work plan:

In general, the Work plan was accepted due to the agreement to follow the default track for finalisation of the revision of the standard. Next (second) meeting is scheduled to 2nd – 4th of June, in Geneva, ISO Head Quarter.

- The third meeting is planned to 18 20 August in Geneva, ISO Head Quarter.
- The forth meeting is planned to 26 28 January 2016 (may be changed due to APLAC-meeting)

#### **Background documents:**

The starting point for the discussions at this meeting was the present version of ISO 17025.

ILAC and EUROLAB had submitted different documents, which were distributed before the meeting. It showed up, that NCSLI also had submitted at least one document, which were not distributed.

ILAC – and other – documents to be included when relevant – the relevant requirements will/can be incorporated in the revised standard. The standard will NOT include any direct requirements to accreditation.

Another background document is the ISO PAS document, which content WG 44 shall handle, because the document contains several "Obligatory Requirements" that cannot be avoided. One example is the management system which either can be ISO 9001 certified or follow requirements in ISO 17025, which is a concept known from e.g. ISO 17020.

Impartiality is another obligatory requirement that will be difficult to handle for the (first and second party) laboratories.

The PAS-document and the obligatory requirements are very essential in the future discussion for revision of the standard.

The overall structure of the standard to be in line with ISO/CASCO requirements (other CASCO standards). The new structure cannot be omitted, unless deviations is granted due to very strong arguments from the group. WG 44 decided to continue with new structure, although several members of WG 44 not were happy with that decision.

To manage the discussion, WG 44 was divided into three subgroups, each to make proposals for transferring existing section/subsection in ISO 17025 into the new structure for the revised standard. Each group was managed by one of the three conveners. The outcome of the discussions were presented in full WG at the end of day one. Since it - so far - did not had any content, Item 8 "Information Requirements" in the new structure were omitted for the purpose of ISO 17025.

#### Day two - continuing the discussion on the structure.

The discussion on the result from each of the three groups on day one showed that there are some agreement on where to place what in the new structure. Discrepancies may be due to different understanding of the headings in the new common structure. At this stage, the discussion very easily got into many details.

- Group one managed by Heribert Schorn: Scope, Structural, and Resources
- Group two managed by Steve Sidney: Process
- Group two managed by Warren Merkel: Management

The EUROLAB representatives joint the Process group. After thorough discussions, the group agreed on the outline/headings for section 9 Process, as they are given in Annex.

## Day three - discussion of outcome from day two.

At the beginning of day three, the convener made it clear, that the very first Working Draft will be finalized during this meeting, and solely based on the requirements in the existing version of the standard. EUROLAB and other background documents will only be included as comments.

**Conclusion:** The drafted document will be distributed among the WG-members for internal WG 44 commenting. The document will be distributed in pdf-format via e-mail, together with a link to the commenting web page. The members of WG 44 will have 4 to 5 weeks to comment, and all comments will be circulated to the group. It was highlighted, that "only" major area of concern to be commented during the commenting process. Proposals on "additions", e.g. distinguishing between validation and verification, has to be included in the commenting process. A drafting group will be established at the next meeting, and their first meeting will take place in November 2015.

One interesting statement from Jean Mac Curtain during the meeting: "CASCO produces competence standards – not management standards".

Generally, the EUROLAB representatives got rather good attention and feedback on the Cook Books and White Paper – although none of them were discussed during the (official) meeting.

## **Personal Developments**

- Hana Šmardová replaced Jiří Rozsíval as the SZU director of economics & operations. In this position, she will be directly responsible to Tomáš Hruška, Director-General of SZU.
- Chris Kirk wishes to relinquish his position as Chief Executive Officer of the SGS Group. He will be
  proposed as a director at the next Shareholders Meeting to be held in Geneva on March 12, 2015, at which
  time he will officially relinquish his responsibilities as Chief Executive. Effective that date, the Board will appoint Frankie Ng, currently Executive Vice President for SGS Industrial Services as the Group's new Chief
  Executive Officer.
- Michael Fübi assumed the role of Chairman of the Executive Board of Management for TÜV Rheinland AG on January 1, 2015.

## **Upcoming EUROLAB Events**

- TCQA, 8th April 2015, Odense, Denmark
- **EUROLAB Board meeting,** 8th April 2015, Odense, Denmark
- EUROLAB workshop & 25th Anniversary Celebrations, 9th April 2015, Odense, Denmark
- EUROLAB General Assembly, 10th April 2015, Odense, Denmark
- JTC PTC, 27th-28th April 2015, Milan, Italy
- **EUROLAB Communication Committee meeting,** 15th June 2015, Brussels, Belgium
- **EUROLAB Board meeting,** 16th June 2015, Brussels, Belgium
- CEOC International—EUROLAB—IFIA Safety Seminar 2015, 10 November 2015, Brussels, Belgium



Odense, Denmark

### **International Events**

- CAB College meeting in Brussels, 14 April 2015
- EAAB meeting in Brussels, 15 April 2015
- Joint IAF-ILAC Mid-term Meetings in Frankfurt, 9-16 April 2015.
- ISO CASCO WG 42 (Revision ISO/IEC 17011) meeting in Geneva, 11-13 May 2015
- Intertek Seminar 'European food contact regulations Do your materials and products comply?' in Amsterdam, 23rd-24th April 2015
- EA General Assembly in Athens, 27-28 May 2015
- CEOC General Assembly in Cologne, 30th May 2nd June 2015
- 8th International Working Conference "Total Quality Management Advanced and Intelligent Approaches" in Belgrade, 2-5 June 2015
- EA Laboratory Committee meeting in Belgrade, 8 September 2015
- EA Horizontal Harmonization Committee meeting in Brussels, 24-25 September 2015
- 2015 International Congress of Metrology in Porte de Versailles in Paris, 21-24 September 2015
- EA Certification Committee meeting in Lisbon, 6-7 October 2015
- EA Inspection Committee meeting in Lisbon, 8 October 2015
- CAB College meeting in Brussels, 20th October 2015
- EAAB meeting in Brussels, 21st October 2015
- ILAC-IAF Joint Annual Meetings in Milan, 28 October—6 November 2015
- EA General Assembly in Budapest, 25-26 November 2015

## **International Events**

## 9th UILI Inter-Laboratory Practice 2015 – "Metals in pure water (drinking water)"

The Union Internationale des Laboratoires Indépendants (UILI), ILP Committee is currently organising the 9th International Laboratory Practice 2015, a global comparative study of laboratory analysis. The 2015 proficiency test will focus on the analysis of metals in pure water. The methods of testing for each laboratory are free.

Time schedule:

(a) Deadline of application: End-February, 2015(b) Distribution of test samples: End-March, 2015

(c) Deadline of reporting: June 30, 2015 (d) Issue of final report: October, 2015

In order to register please send an email to Mrs. Melissa Fernández Valero (UILI secretary) secretariat@uili.org or register directly on the UILI website www.uili.org.

For further information regarding the participation fees and additional practical details you can download the official announcement from our website: http://www.eurolab.org.



## **PEFTEC 2015 Exhibition and Conference**

International Labrate is organising the Petroleum Refining and Environmental Monitoring Technologies Conference & Exhibition (PEFTEC) to be held in Antwerp on 18-19 November 2015. EUROLAB is a partner of this event.

PEFTEC 2015 Exhibition and Conference is for Companies specialising in monitoring and analytical technologies for the Petroleum, Refining and Environmental Industries.

The two day conference, seminar and poster programme will focus on:

- Standards & Quality Assurance
- International & Industrial Regulation
- Analytical Techniques: General
- Analytical Techniques: Separation Science
- Analytical Techniques: Elemental Analysis
- Online & Process Monitoring
- Environmental Monitoring and Treatment of Water, Air or Soil
- Sensors and Remote Monitoring
- The deadline for submitting papers is the 24th of April.

Entry to the exhibition at PEFTEC 2015 is free to all Pre-Registered Visitors.

PEFTEC has launched the call for papers for the technical programme at the event which is open until 24th April. The abstracts can be submitted by following the <u>link</u>.

For further information regarding programme, registration and other practical details please visit the official website of PEFTEC 2015 Exhibition and Conference <a href="http://www.peftec.com/index/">http://www.peftec.com/index/</a>.

