LEGISLATION AND NORMS

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R.G. Visser

Standardization news: NEN 7777 – Standardisation of the validation process

In Holland a working group (WG) of analytical experts under the coordination of the Dutch Standardisation Institute (NEN) is preparing a new Dutch Standard (NEN 7777) in an effort to standardise the validation process of an analytical method.

The need for this project comes from problems with audits during the accreditation of analytical laboratories. Neither ISO 45001 nor ISO 17025 contains a detailed description of a validation process. Also, besides general statistical methods, there is no written standard procedure to verify the soundness of any measured performance characteristic.

This new standard procedure NEN 7777 will be complementary to ISO 5725. While ISO 5725 describes some detailed interlaboratory procedures for the determination of the repeatability and the reproducibility of an analytical method, NEN 7777 will cover intralaboratory procedures for the determination of a number of performance characteristics of an analytical method like repeatability, trueness, limit of detection, limit of quantification, etc. Furthermore, detailed procedures to statistically test the measured performance characteristics against literature values will be present.

The project is already in its final stage and a draft of NEN 7777 is planned for the middle of 2001.

ISO 17025 and measurement uncertainty

In the new ISO 17025 a clause is present that requires all accredited laboratories to prepare a procedure for the estimation of the measurement uncertainty of all accredited tests. However, a detailed procedure is not given. Several guidance documents have already been prepared (e.g. by VAM and EURACHEM) and some example procedures have been published (also in ACQUAL).

However, the Dutch laboratories did have serious doubts on the feasibility of the procedures as described in these documents. At the annual general meeting of EURACHEM, Netherlands, in cooperation with the Dutch Accreditation Board (RvA), several WGs were set up which are presently discussing practical solutions to tackle the foreseen problems and to comply with the requirements of ISO 17025 on this subject.

In autumn 2001, the four WGs for petroleum, environmental, pharmaceutical and food laboratories will present their findings at a general workshop in order to try and get a consensus. Thus it is hoped that the RvA auditors will find a limited range of procedures for the determination of the measurement uncertainty on their visits to the various accredited laboratories in Holland. And also the laboratories will hopefully not be surprised by odd personal interpretations by the RvA auditors during their accreditation audits.

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MEETING REPORT

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Belinda L. Collins

ILAC 2000 – Washington, 28 October – 3 November, 2000 Reflections of the Immediate Past Chair of ILAC

It was a real pleasure to chair the International Laboratory Accreditation Cooperation (ILAC) for the past 2 years as it continued its transition from a conference to a cooperation. The highlight for me, of course, was ILAC 2000, hosted by the National Institute for Standards and Technology (NIST) and others in North America in the Washington, D.C. area, from 28 October to 3 November, 2000.

One of the biggest achievements of ILAC 2000 was the seminar on laboratory accreditation sponsored by NIST and funded by the United States Department of Commerce, NIST, the Asia Pacific Economic Cooperation (APEC), and ILAC. More than 40 representatives of developing accreditation bodies from Russia and the newly independent states, Latin America, the Asia-Pacific region, and Africa attended the seminar and observed much of the General Assembly. As an immediate result, four new accreditation bodies among these representatives have joined ILAC as associate members, and more are expected in the near future.

ILAC 2000 continued ILAC's on-going technical concentration with seminars on "The Application of ISO/IEC 17025: Determining the Competence of Testing and Calibration Laboratories", "Stakeholder Reliance on Accredited Laboratories", "Proficiency Testing and Interlaboratory Comparisons", "Uncertainty and Traceability", and "Effect of Accreditation on International Trade". ILAC 2000 also hosted two special seminars – one on uncertainty analysis and the other on development of accreditation bodies.

The climax of the ILAC 2000 General Assembly, which followed the technical conference, was the signing of the ILAC Arrangement by 37 members from 28 economies. This long-awaited arrangement extends the current regional arrangements to a global one, and is a key step in facilitating one-stop testing with minimal extra cost. During ILAC 2000, ILAC also signed an agreement with the United Nations Industrial Development Organization (UNIDO) to facilitate outreach and training to developing laboratory accreditation bodies around the world. This cooperative effort will enable ILAC to provide even more effective outreach to developing economies throughout the world. ILAC now has strong ties to UNIDO, to the me-

trology organizations of Bureau International des Poids et Mesures (BIPM) and the Organisation Internationale de Metrologie Legale (OIML), to the testing community of the International Electrotechnical Commission (IEC) through our liaison with the IEC-Conformity Assessment Board (CAB), to the policy developments in the International Organisation for Standardization (ISO) through our category A liaison status with the Committee on Conformity Assessment Standards (CASCO), and to the certification community represented in the International Accreditation Forum (IAF).

ILAC members can say with pride that ILAC has cemented its role as the international body concerned with laboratory accreditation. ILAC members continue to work to ensure the accuracy of test and calibration reports and guarantee the importance of laboratory accreditation as an essential element for underpinning successful international trade. ILAC is truly the worldwide resource for technical information needed to support effective laboratory accreditation. ILAC technical seminars that provide material that is later incorporated into ISO/IEC Guides and Standards; our experts serve on the technical committees that write these documents.

ILAC 2000 was a memorable event for all of us, especially me. I deeply appreciate the support that ILAC members have given me during my chairmanship of ILAC and look forward to continuing to work with all of you.

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NEW REFERENCE MATERIALS

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Jean Pauwels

Latest news on BCR/IRMM reference materials

Institute for Reference Materials and Measurements (IRMM) catalogue of Bureau Communautaire de Reference (BCR) reference materials

The 2000/2001 catalogue of BCR reference materials published during the second-half of 2000 has now been updated on a "European Reference Materials" CD ROM (including the Bundesanstalt für Materialforschung und -prüfung – BAM –, Laboratory of the Government Chemist – LGC – and IRMM/isotopic reference materials catalogues) made available in March 2001 at the occasion of Pittcon-2001 in New Orleans (USA). Moreover, a permanently updated version of the IRMM catalogue of BCR reference materials, as well as all related certificates and safety data sheets (SDS) is available on the IRMM/BCR website: (http://www.irmm.jrc.be/mrm.html).

The latest update on the internet contains the new items below.

Trace elements in polyethylene (BCR-680/681)

In 1993 IRMM certified – in collaboration with the Verein der Automobilindustrie (VDA) – a set of four certified reference materials (CRMs) for Cd in polyethylene. In January 2001, a new set of two polyethylene CRMs was certified by BCR for two concentrations of As, Br, Cd, Cl, Cr, Hg, Pb and S. The certification of these materials was based on a laboratory intercomparison within the framework of a SM&T shared cost action carried out under the scientific guidance of IRMM.

Polychlorinated biphenyls (PCBs) in pork fat (IRMM-444 to 446)

In March 2000, a set of three CRMs for PCBs in pork fat, containing total PCB mass fractions of <14, 93 and 207 µg/kg, respectively, was certified by IRMM. The certification was based on a laboratory intercomparison using gas chromatography GC- isotope dilution mass spectrometry (ID)MS organised by IRMM within the framework of a JRC-support action to combat the "Belgian dioxin crisis".

CRMs for biotechnology (IRMM-413)

As a complement to the existing set of genetically modified organism (GMO) CRMs certified earlier (IRMM-410R: Roundup ready soy; IRMM-411: Bt-176 maize; IRMM-412: Bt-11 maize), a new set of six dried maize powder CRMs, containing genetically modified MON810 maize with GMO-mass fractions of <0.02%, 0.1%, 0.5%, 1%, 2% and 5%, was certified by IRMM in January 2001. To minimize DNA degradation during production, this third-generation GMO reference material was produced with the help of a new dry mixing technique.

BCR-194, -195 and -196 (Pb and Cd in bovine blood) re-certified for Cd

The Cd content of BCR-194, -195 and -196, originally certified by BCR in November 1985, was re-certified in December 2000 on the basis of in-house IRMM measurements carried out by means of isotope dilution inductively coupled plasma mass spectrometry (ICP-MS), used as a primary method of measurement. To ensure correctness of the results, two different methods (direct measurement of the digest and measurement after matrix separation by ion chromatography) and two different digestion methods (microwave and high pressure ashing) were used. The combined results of these measurements were not significantly different for the materials with the higher concentrations (BCR-195 and –196), but below the originally certified value for BCR-194 (0.20❑0.05 µg/l instead of 0.5❑0.1 µg/l). The certified lead concentrations remained unchanged.

Total glucosinolate and sulphur content of three rapeseed materials (BCR-190R, -366R and -367R)

Three rapeseed (colza) CRMs (BCR-190, -366 and -367), originally certified by BCR