



SPOTLIGHT

CALIBRATION SPECIALISTS LTD.

With INAB reminiscing on its 21st year in Accreditation, we put the spotlight on one of our first and longest accredited members, Calibration Specialists Ltd.

Eleanor Noonan, Quality Manager of Calibration Specialists Ltd gives an overview of the last 20 years.

Calibration Specialists Ltd was the first applicant to the Irish National Accreditation Board (INAB) or Irish Laboratory Accreditation Board (ILAB) as it was previously. The Laboratory was the first accredited company under the scheme, being awarded its accreditation under the prestigious registration number 001C in 1987. As the longest serving member, Calibration Specialists Ltd. have been maintaining and expanding their schedule of accreditation for over 20 years.

Because of our measurement expertise we have been able, through our sister company Feasa Enterprises, to design and manufacture an instrument to measure the colour and intensity of Light Emitting Devices (LEDs). We have recently been awarded a European Patent for this product (Patent No. 1,277,383) which is currently being sold in Europe, Asia, the USA and China.

21 years has seen significant changes within the Irish National Accreditation Board including signing up to multilateral agreements in Europe through the European Cooperation for Accreditation (EA); the introduction of ISO17025; and the introduction of ISO17025:2005.

We are pleased to have been associated with the development of the calibration industry in the country over the last 20 years and look forward to meeting the requirements and challenges of the industry and accreditation for years to come.

For full details on Calibration Specialists Ltd, Scope of Accreditation and contact details consult the website at <http://www.inab.ie/schemes/directory.html>

ERS – FIRST ACCREDITED PERSONNEL CERTIFICATION BODY IN IRELAND

Andrew Stratford – Accreditation Officer

In March 2006, Senator Mary O'Rourke presented European Registration Scheme for Personnel Competence (ERS) with their accreditation certificate from INAB. ERS is the first certification body to be awarded accreditation by INAB in compliance with I.S. EN ISO/IEC 17024:2003, "Conformity Assessment – general requirements for bodies operating certification of persons".



Pictured are Eleanor Noonan, Quality Manager and Tony O'Meara, Technical Manager of Calibration Specialists Ltd.

Accreditation has proved a valuable marketing tool for the laboratory, allowing the laboratory to tender for contracts assuring the customer of an independently verified laboratory. The accreditation is recognised both nationally and internationally as a mark of a laboratory's competence to carry out the measurements on its accredited schedule.

Throughout those 20 years the drivers for achieving and maintaining accreditation have not changed. Clients are confident that they have a reliable calibration laboratory carrying out their calibration with the flexibility to meet their specific individual needs. INAB regularly assess factors relevant to the laboratory's ability to produce accurate calibration data, including the technical competency of the laboratory; appropriateness of methods; traceability of calibrations to national or international standards; suitability, calibration and maintenance of reference test equipment; environment; transportation and handling of test items; and quality assurance of calibration data.

Accreditation has evolved over the past 20 years; today it is common practice in many industries, such as the medical device and healthcare industries, to specify accreditation as a requirement for the providers of calibration services. The customer is aware that using an accredited laboratory has added value for them by:

- Minimizing risk
- Avoiding expensive retesting
- Enhancing their own customers through audit
- Reduction of costs
- Acceptance of results internationally
- Product Quality Assurance



Pictured (from left to right) are: John Senders, ERS; Senator Mary O'Rourke and Jim Bell, ERS.

ERS, headquartered in the UK and with an assessment centre in Ireland, operates Personnel Registration and Certification schemes to ensure personnel are competent within their particular field. The personnel assessments are conducted to strict documented requirements in their assessment centre in Finglas, and take the form of theoretical and practical examinations, which evaluate the technician's skills.

INAB accreditation was awarded to ERS to undertake certification of persons in accordance with the Guild of Gas Fitting Operatives (GGFO) scheme 00445910131-1; the fitting of domestic gas installations in accordance with I.S. 813:2002. Accreditation ensures that the assessments by ERS demonstrate an individual person's competence with credibility and consistency.

For further information on their scope of accreditation, check out <http://www.inab.ie/schemes/directory.html>

INTERNATIONAL NEWS

EA Multi Lateral Agreement Committee (MAC)

Adrienne Duff – Accreditation Officer

The MAC meeting was held in Amsterdam on 4th and 5th April 2006. The committee comprises of representatives from the members of the (EA) European co-operation for Accreditation and associate members. Tom Dempsey and Adrienne Duff attended on behalf of INAB.

One of the main functions of the MAC is to review the evaluations of EA accreditation bodies either to maintain and/or extend their signatory status for the multi lateral agreements (MLA). The evaluations for seven accreditation bodies along with a pre-evaluation report were considered by the committee. Each accreditation body (AB) is evaluated for compliance with ISO17011 by a peer review team appointed by the MAC. The evaluation report which documents the operation of the AB along with any findings identified is presented. Evidence of corrective actions implemented by the AB is also presented and discussed. The MAC then decides on the MLA signatory status for the AB.

INAB underwent its recent evaluation in February 2006.

Other matters discussed at the meeting in April included cross-frontier policy and developments designed to improve the evaluation process. The next meeting is scheduled for October 2006.

INAB HOST EA FOOD COMMITTEE IN DUBLIN

Andrew Stratford – Accreditation Officer

INAB hosted the EA Food Committee in Dublin on the 17th and 18th May 2006. This committee was attended by representatives from a number of EA Accreditation Bodies. One of the areas discussed at the meeting was a consistent approach to accreditation to the ISO 22000 standard – Food safety management systems – requirements for any organization in the food chain. Other topics discussed were organic farming and new food quality products, dealing with such issues as:

PDO (Protected Designation of Origin) covers the term used to describe foodstuffs which are produced, processed and prepared in a given geographical area using recognised know-how.

In the case of the PGI (Protected Geographical Indication) the geographical link must occur in at least one of the stages of production, processing or preparation. Furthermore, the product can benefit from a good reputation.

TSG (Traditional Specialty Guaranteed) does not refer to the origin but highlights traditional character, either in the composition or means of production.

For further information
http://europa.eu.int/comm/agriculture/foodqual/quali1_en.htm

EA WORKING GROUP IN LABORATORY MEDICINE

Adrienne Duff – Accreditation Officer

The working group met in Vilnius, Lithuania on 22nd and 23rd of May and the meeting was attended by Adrienne Duff on behalf of INAB. This working group reports to the EA Laboratory Committee and is currently chaired by Dr. Andreas Steinhorst of DACH. The group is comprised of members of the EA Accreditation Bodies and representatives from the stakeholder medical profession. The agenda was extensive and included discussions on how to improve the organisation of meetings, consistent formatting of scopes and the impact of new directives and sector requirements on the accreditation of medical laboratories. Most importantly there was extensive discussion on the technical requirements of ISO 15189 and significant sharing of experiences. It was agreed that the group will publish a "live" document which will capture the consensus decisions made by the group on each clause of the standard. INAB will make this information available on its website in due course.

The next working group meeting is provisionally scheduled for 7th and 8th December in Berne, Switzerland.

OVERVIEW OF NEW INAB POLICIES

Over the period April and May 2006, INAB released a number of new policies. The arrival of these new policies was announced on our website in March 2006. All new and existing policies can be downloaded from our website at www.inab.ie/publications.asp Below is a synopsis of the new policies which are now in place.

Policy for organisations undertaking work in an area which is regulated by legislation – PS12

Andrew Stratford – Accreditation Officer

Conformity Assessment Bodies (CABs) may be accredited to undertake a conformity assessment activity which may sometimes be required to be undertaken in an area regulated by legislation. This applies primarily to laboratories, but could also apply to other conformity assessment bodies.

INAB considered that this area would benefit from the policy statement to assist our accredited CABs. So, to simplify matters, rather than taking a prescriptive approach, INAB will now expect CABs to determine the extent to which the requirements apply to their accredited activities and ensure that they comply with all that are applicable. The CAB should then ensure that it fully understands the purpose for which the customer requires the work to be undertaken, and to discuss with the customer any legislative or other requirements that may have an impact on how the service has to be carried out, making transparent to the customer the extent to which the CAB can meet the needs of the customer with respect to such matters.

At assessment visits INAB will examine records, to be satisfied that the customer was apprised of the legislative impact that applied to their request and the extent to which the CAB was capable of providing the requisite service under its scope of accreditation.

Policy on the Performance of in-house calibrations – PS 13

James Stapleton – Accreditation Officer

INAB has developed this policy statement to address the issue of in-house calibrations carried out by organisations accredited for calibration, testing or inspection activities. It is recognised that while most organisations prefer to use the services of external accredited laboratories to perform these calibrations, some calibrations are carried out in-house.

It is essential that in-house calibrations are carried out competently and provide appropriate traceability. This policy statement outlines the requirements that organisations must meet and which include: environment; training; standards; procedures; measurement uncertainty budgets. The assessment of in-house calibrations will wherever possible be covered as part of the traceability and calibration aspects within normal assessment/surveillance activities, but in certain circumstances specialist calibration assessors may be required. The assessment procedures used will include document review and on-site witnessing as appropriate.

The ability to perform in-house calibrations will not be included in the published schedule of accreditation. Organisations are required to include all in-house calibrations in their audit programmes and provide INAB with a list of instruments calibrated as part of the submission of documentation prior to an INAB visit.

Policy on assessment of quality system documentation and data in an electronic environment – PS 14

Andrew Stratford – Accreditation Officer

A growing number of applicant and accredited organisations are storing and transmitting their management system documentation and data in electronic format. This can involve portions of the management system or the entire system.

The aim of the policy statement is to provide guidelines for organisations and assessors with the aim of ensuring that electronic systems for management system documentation meet the requirements of the relevant accreditation standard, including full audit trail requirements.

PS 14 describes a set of requirements which should be followed by the accredited organisation. It covers aspects that would be expected of any management system in an electronic environment, such as security, confidentiality and access control, backup, anti-virus, unique identification of documents and records, etc.

Assessment of electronic quality system documentation is an integral part of INAB's normal assessment/surveillance/re-assessment process for all applicant and accredited organisations.

Whether the system is commercially available or bespoke, INAB expects organisations to provide documentation covering (as applicable), details of implementation, testing/validation, training, agreements with external IT suppliers, etc. This information will be reviewed in INAB, where a decision will be made as to whether an additional IT expert should be part of the assessment team.

NEW BOARD MEMBER APPOINTED



Vagn Andersen, Manager of International Affairs, DANAK

I am very pleased at my recent appointment as a Member of the Board of INAB. Forfás demonstrates, by nominating me to the INAB Board, that accreditation is an international activity and accreditation in Ireland shall be operated in accordance with internationally agreed practice.

My approach to the work on the INAB Board will be an international one. I have worked with DANAK, the Danish Accreditation Board since 1997 and have a wide experience in how the Danish accreditation scheme is used by public authorities and the private sector.

I have a great knowledge of accreditation in other European countries, and globally through participation in the international cooperation between accreditation bodies in the European co-operation for Accreditation (EA), International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF). The international discussion on the accreditation criteria and a harmonized application of the standards and guidelines is useful in implementing the accreditation criteria at the national level, and I hope my knowledge in this field will be of use for the Board and INAB.

For the last 3 years I have followed the discussion in the Senior Officials Group for Standardisation committee (SOGS) on the EU Commissions approach to accreditation and the need for further harmonization at the European level of the assessment of notified bodies. A decision by the European Council in the near future urging Member States to apply accreditation as the recognised tool for assessing the technical competence of notified bodies will be a challenge for accreditation bodies at the national level as well as for EA. I am looking forward to dealing with this challenge in Ireland, and Denmark and in the EA.

In 1984, I graduated in Economics from the University of Aarhus in Denmark and worked for 11 years in the Danish Financial Supervisory Authority as a Bank Inspector, meeting the requirements in Danish legislation and European directives. During that time I spent one year in the Bank of England studying the UK implementation of the directives in the regulation for UK banks.

From 1995 – 1997, I worked with the Danish Export Credit Fund setting up an administration division.

I am looking forward to working as a member of the INAB Board.



ACCREDITATIONS AWARDED IN 2005

- 171T **Central Meat Control Laboratory**
Backweston Laboratory Campus, Young's Cross,
Celbridge, Co. Kildare
Chemistry & Biology Testing Laboratory
- 5008 **Samuin Standards Institute Ltd**
34 Green Road, Blackrock, Co. Dublin, Ireland
Via del Sale, 13, 26100 Cremona, Italy
- 172T **En-Force Laboratories Ltd.**
Unit G, Ballyvolane Business Park, Spring Lane,
Ballyvolane, Cork
Biological Testing Laboratory

INAB ANNOUNCEMENT

Orla Doyle – Project Executive

As part of our celebrations for our 21st, INAB will be hosting a Celebratory Evening, in Dublin Castle on 11th October 2006.

Over the summer, we will be issuing invitations to all our applicant and accredited organisations, associated industry and special interest groups to join us to mark this milestone.

Our speaker program includes Mr. Michael Ahern TD, Minister for Trade and Commerce, and Mr. Lorenzo Thione, Chairman, European Cooperation of Accreditation (EA). We anticipate that we will also have a representative from the European Commission.

We look forward to celebrating our 21st with you in October.

ISO 17025:2005 TRANSITION

INAB has been assessing the new version of the standard since November 2005, but as a transitional arrangement between then and June 2006, any deviations from the standard are recorded as observations rather than non-compliances. However, any such observations must be cleared by June 2006.

With that deadline just around the corner, this is just a reminder to the laboratories that did not transfer immediately to the new standard – please ensure that resolutions to observations that were raised against the new standard are submitted to your Accreditation Officer in INAB.



STAFF NEWS – NEW FACES

INAB WELCOMES 3 NEW ACCREDITATION OFFICERS



Sinead Guckian

Frank Crowe

Emma Scott McGrane

INAB would like to wish Catherine McEnri every success, with her recent transfer to Forfás policy division on a career development opportunity for nine months.

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