The INAB Standard

www.inab.ie
THE NEWSLETTER OF THE IRISH NATIONAL ACCREDITATION BOARD

June 2013
EDITION 31

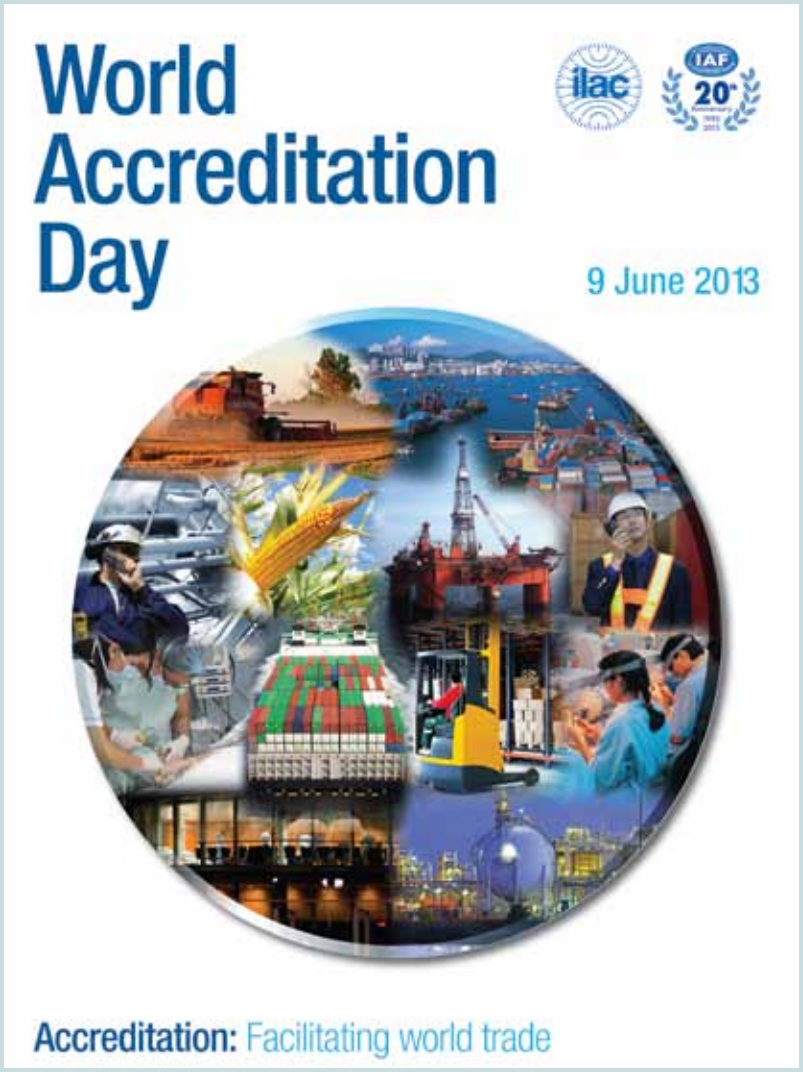
WORLD ACCREDITATION DAY – FACILITATING WORLD TRADE

World Accreditation Day will take place on 9 June 2013 and this year the focus is on the important role accreditation plays in facilitating trade around the world, both within and across national borders.

As international trade has grown, so too have the number of national and international voluntary and mandatory technical regulations, standards, testing, inspection and certification procedures across all market sectors which apply to samples, products, services, management systems or personnel.

Generally, these are introduced to meet the legitimate requirements of quality and safety that consumers, businesses, regulators and other organisations demand of goods and services, whatever their country of origin.

It is vital, not only for individuals and organisations but for national and international economic health, that products and services can cross borders to meet global demand without causing undue risk to the health and security of individuals or the environment.



https://www.ilac.org/documents/WAD-2013/WAD_Brochure_Med_Res.pdf

NEW EUROPEAN CO-OPERATION FOR ACCREDITATION CHAIR

Mr Thomas Facklam – European Co-operation for Accreditation Chairman

Thomas Facklam from DAkkS, the German national accreditation body, was elected as the new EA Chairman at the General Assembly on 21-22 November 2012 in Bratislava, Slovakia.

THE IMPORTANT ROLE OF THE EA PEER EVALUATOR

INAB currently has four qualified EA peer evaluators on its staff. INAB are obliged, as a signatory to the EA Multi-lateral Agreement (MLA), to carry out a number of evaluations each year for the European Co-operation for Accreditation (EA). **EA peer evaluators** are highly qualified, experienced accreditation body staff members who attend training programs on a frequent basis. Two to three training seminars take place every year. Peer evaluator performance is reviewed regularly by the EA MAC management group and EA peer evaluators can be mandated for peer evaluation at the ILAC or IAF levels.

European co-operation for Accreditation

Who is evaluated?

Normally, every four years accreditation bodies that are signatory to the EA Multilateral agreement (MLA) are subject to a rigorous evaluation by EA.

What are accreditation bodies evaluated against?

Accreditation bodies are evaluated against the international standard ISO/IEC 17011, and other relevant standards and related criteria such as application documents from EA, ILAC or IAF, and applicable criteria on behalf of European or National Regulators and industrial schemes. The MLA process is overseen by the European Commission, the EA Advisory Board and the national authorities.

Why are these evaluations so important?

The main objective of the peer evaluation activities is to evaluate the on-going compliance of the national accreditation bodies to the internationally agreed requirements and to ensure that regulators, stakeholders and the business community can have confidence in certificates and reports issued by conformity assessment bodies under the EA MLA.

Who operates the peer evaluation system?

EA has been recognised by the European Commission according to Article 14 of **Regulation (EC) nº 765/2008** *"Setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) 339/93"* to operate the peer evaluation system of national accreditation bodies in Europe.

When will INAB be evaluated?

INAB were evaluated in 2010, and our next peer evaluation will take place in 2014.

ANDREW STRATFORD – EA PEER EVALUATOR

Andrew gives us an insight to the role of evaluator

What does the EA peer evaluator do?

For each evaluation of an accreditation body, peer evaluators are selected from several other accreditation bodies, ensuring conflicts of interest are avoided. An EA peer evaluation team usually comprises at least six people, covering laboratory testing and calibration, inspection, management system, product and personnel certification. Each evaluator on the team is assigned one area of responsibility; for example, laboratory testing. The evaluator typically witnesses at least one assessment by the AB being evaluated, and also spends time at the AB's office reviewing client files, procedures and records against requirements of ISO 17011 and the AB's own internal procedures.

How long does the evaluation last?

An EA peer evaluation typically lasts for five working days on site. The evaluation team typically meets for a few hours on the Sunday before the evaluation begins, and frequently spends the Saturday afterwards drafting the report.

How do you get assigned?

Potential candidates are proposed to the EA MAC Secretariat and if they fit defined criteria, they attend specific "Newcomers" peer evaluation training. After that, the candidate is included on an evaluation team as a trainee, and if his/her performance is satisfactory, is included as a full team member on the next evaluation. Assignment as a team member on each peer evaluation is done by EA MAC Secretariat, based on competence, availability, geographical area, etc.

What are the benefits to the evaluators, AB, the Accreditation world?

The evaluators have the opportunity of seeing how things are done in other accreditation bodies. Experience gained in the evaluation of other ABs invariably broadens an individual evaluator's approach to conformity with the various accreditation standards.

Benefits to the AB under evaluation:

- There is an opportunity to improve, where areas of improvement are identified by the evaluation team.
- Where things are done well, there is endorsement of this by a third party.
- International recognition and competence confirmed.

INAB's participation in the peer evaluation activity ensures that INAB maintains its respected reputation in the EA and International community.

BREASTCHECK WESTERN UNIT, GALWAY AWARDED ACCREDITATION

On the 19th February 2013, BreastCheck Pathology Department, Galway were accredited by INAB to undertake testing as detailed in their scope, registration number 306MT, in compliance with the International Standard ISO 15189 "Medical Laboratories – Particular requirements for quality and competence".

(L-R) Caroline Glynn, Iria Vázquez Rodríguez, Dr Margaret Sheehan and Marie Hynes.
Staff at the BreastCheck Pathology Unit of the BreastCheck Western Unit with their recently awarded Accreditation Certificate.

INAB ROLLOUT 2ND PHASE OF ORGANISATION EXTRANET

INAB is currently undertaking a pilot project to investigate the use of an Extranet, that allows Organisations upload documentation which are accessible by the INAB Assessment Team.

The initial trial took place with seven organisations and 12 assessors in 2012. A survey of these organisations and the assessment teams involved took place.

It was agreed in February 2013, following analysis from all participants of 2012 phase, to roll out a 2nd pilot phase to broaden the trial.

Over 20 organisations have been invited to participate.

Overall it has been a very positive project and it looks very likely that this will be rolled out to all.

EXPRESSIONS OF INTEREST

INAB welcome receipt of expressions of interest from experts seeking to provide contracted professional technical services to INAB in support of its accreditation programmes.

Expertise demand will vary from time to time but INAB would welcome contact from potential assessors in the following sectors: Food, environment, construction materials testing, calibration, forensic science, medical testing and technical expertise to assess building air tightness/ building air leakage permeability testing to BS Standards.

The full range and scope of activities is documented on www.inab.ie

Candidates should have a third level qualification and greater than five years experience working in the applicable sector. Formal assessor training and previous experience working with an accreditation body would be a distinct advantage.

If interested, please complete the IP25 EX form, which is available in the "**contact us**" section on the website.

INAB TRANSITION PLANS – MEDICAL/CERTIFICATION

A number of accreditation standards have undergone revisions including standards ISO/IEC 15189; ISO/IEC 17065; and ISO/IEC 17024 which impact medical laboratories and certification bodies.

Each organisation has been sent a Transition Statement which outlines the plan for their relevant standard.

Each organisation is required to put in place an action plan.

As a minimum action plans shall include:

1. All specific actions to be taken to implement the changes.
2. The timeframe for completion of such actions.
3. The persons responsible for the actions.
4. Process in place to monitor progress and completion of the actions.

The Accreditation Certificate and Schedule of Accreditation will be adapted to reflect accreditation against the relevant standard after the surveillance/re-assessment has been successfully completed and a decision for renewal of accreditation has been granted. The accreditation number will remain the same. The date on the certificate will be the date of the decision to grant accreditation for the new standard.

It is the responsibility of each organisation to familiarise itself with the new standard and implement the changes necessary to comply with the standard.

Organisations may obtain a copy of the relevant standard from:

ILI, 42-44 Northumberland Road, Dublin 4.
Tel: (01) 857 6730 Fax: (01) 857 6729
www.standards.ie

INAB looks forward to implementing the new standard(s) and working with organisations to ensure a smooth transition.

	Transition Plans			
	ISO/IEC 15189:2012	ISO/IEC 17065:2012	ISO/IEC 17024:2012	ISO/IEC 17020:2012
Submit transition action plan to INAB by:	1st November 2013	15th November 2013	1st July 2013	1st May 2013
Action plan to demonstrate an analysis of the new standard and effective implementation by:	1st May 2014	15th March 2014	1st January 2014	1st Sept 2013
All INAB surveillance/reassessments will be carried out from:	1st May 2014	15th March 2014	1st January 2014	1st Sept 2013
New applicants will be assessed from:	November 2013	15th September 2013	1st January 2013	1st April 2013
Existing accredited labs will be assessed to the current standard between:	November 2013 to May 2014			
Schedule of visits may be altered to ensure that laboratories are verified for compliance by:	1st November 2015	15th September 2014	1st July 2015 (HQ)	1st March 2015
Full details of each transition plan are available on www.inab.ie				

INAB

PROFICIENCY TESTING

Proficiency testing or Inter-laboratory Comparisons are an important surveillance tool for the granting and maintenance of accreditation and are an essential way of meeting the requirements of ISO/IEC 17025 and ISO/IEC 15189 in the area of quality assurance of laboratory results. Accreditation mandates laboratories to participate in proficiency testing or inter-laboratory comparison programmes for all accredited analyses undertaken in laboratories, when suitable programmes exist. Proficiency testing is an objective tool used to assess laboratory competence and acceptable performance must be demonstrated prior to accreditation being awarded and for ongoing maintenance of accreditation.

INAB Policy on proficiency testing is outlined in PS1 and ILAC and EA documents, ILAC-G22, and EA-3/04 G provide information on the use of proficiency testing. INAB also maintains a register of PT providers which lists the PT providers used by INAB accredited laboratories and the register is a valuable source of information when trying to identify a PT provider.

European Accreditation (EA) and other international bodies, such as APLAC, also organise and facilitate PT and ILC schemes. INAB considers that participation in such schemes is an important component of monitoring the integrity of results generated and it is the policy of INAB that nominated accredited laboratories participate in these schemes where they are relevant to their scope of accreditation.

Over the coming months the EA will facilitate a variety of PT schemes, such as photometric measurement on solid State lighting products, water quality – determination of the TON and the TFN of drinking water according to EN 1622:2006, global migration in plastic foil, low-molecular weight heparin (anti-Xa), charpy impact testing, selected priority substances in river sediment (PAH, pesticides, PCB), heavy metals in compound feed, therapeutic drug monitoring (Carbamazepine (CBZ) CBZ-epoxide Clonazepam Lamotrigine Phenytoin), and pesticides in vegetables (grapes). In some cases the participation cost is free and in others cases the cost has to be recovered.

From time to time INAB, in collaboration with the National Metrology Laboratory (NML), organises inter-laboratory comparisons for calibration laboratories. INAB and the NML are currently developing a programme of ILC's that will commence in the second half of 2013 and continue in 2014.

It is hoped that there will be ILC's available in the areas of temperature, volume, electrical, mass, torque, humidity, pressure and balance calibration.

Accredited calibration laboratories may choose to participate in these ILC's or seek ILC's offered by other providers. However, participation in the NML ILC's may be more convenient and cost effective. Where accredited calibration laboratories participate in an NML organised ILC, the laboratory will have to cover the cost of participation as these ILC's will suffice as a substitution for ILC's that laboratories would normally have participated in to comply with INAB policy. Calibration laboratories will be informed of start dates in the near future.

For further information contact Frank Crowe, INAB.

NEW MEMBERSHIP AND RE-APPOINTEMENT ON INAB MEDICAL ADVISORY COMMITTEE (MAC)

In 2010, INAB established the Medical Advisory Committee (MAC) for the sole purpose of offering advice to the INAB Executive on issues of principal importance in accreditation in the medical field. This was primarily in the field of medical laboratory accreditation to ISO 15189, but may expand to other areas of INAB accreditation relevant to the medical sector.

The committee has been in progress for three years and at its recent meeting on 4th March 2013, the existing committee and chair were re-appointed for another three years. The Chair also welcomed two new members Mr David Keane from Bon Secours Hospital Cork and Ms Sinead Kinsella, MedLab Pathology Ltd. The MAC will meet again in June 2013.

Current membership of MAC committee:

Chairperson: Dr Cor de Ruiter

Previous lead and technical assessor from the accreditation body in the Netherlands, RvA.

Ms Marie O'Mahony

Accreditation Officer, Irish National Accreditation Board

Secretariat: Ms Orla Ivers

Project Executive, Irish National Accreditation Board

Mr David Keane

Quality Assurance Manager, Bon Secours Hospital, Cork

Dr Patrick Hayden

Consultant Haematologist, St James Hospital

Professor Martin Cormican

Consultant Microbiologist, Galway University Hospital

Ms Denise O'Neill

Quality Manager, the Mater Hospital

Dr Vincent Tormey

Consultant Immunologist, Galway University College Hospital Galway

Dr Mike Louw

Consultant Clinical Chemist, ClaymonBiomnis Laboratories Ltd

Dr Michael Jeffers

Consultant Histopathologist, Adelaide & Meath Hospital

Dr Sean Cunningham

Joint Working Group on Accreditation

Ms Sinead Kinsella

Laboratory Manager, MedLab Pathology Ltd

MARKS FOR INTERNATIONAL RECOGNITION OF ACCREDITATION

ILAC and IAF have developed marks which can be used by the member accreditation bodies and their accredited bodies under specific conditions set out in a licence agreement.

These marks demonstrate:

- The signatory status to the ILAC and IAF arrangements.
- That the test report or certificate has been issued by a body accredited by a member of the ILAC/IAF arrangement. As such, it can be recognised and accepted by any of these arrangements.

ILAC and IAF Sub Licence Agreement

In March 2013, INAB contacted all our existing accredited clients and advised who were open to use these marks.

The ILAC mark is for use by accredited calibration and testing laboratories. Once you have returned and signed the agreement, you are required to provide an example of the combined logo to INAB before you can use same. It is not possible to use the ILAC MRA mark in relation to the accreditation of inspection bodies at present.

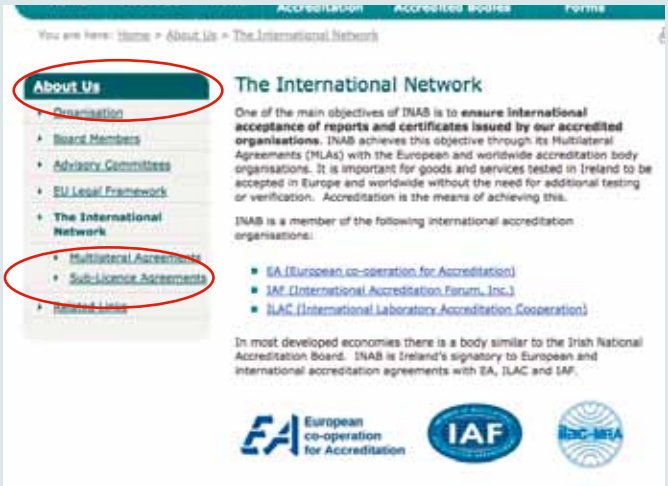
The IAF mark is for use by certification bodies.

How to apply for licence agreement?

Print out two copies of the relevant agreement:

- Sign and return to INAB.
- INAB will sign date and return one copy.
- INAB will make available the electronic copy of the mark.
- ILAC applicants MUST present a combined logo to INAB prior to use of logo.

Log onto www.inab.ie for the application.



ACCREDITATIONS AWARDED IN 2013

306MT	BreastCheck	Galway
307MT	Barrington's Hospital	Limerick
308T	Atlantic Industries Ltd	Co. Waterford
309C	Accu-Science (Ireland) Ltd	Co. Kildare
310C	Smithstown Light Engineering	Co. Clare
311C	Environmental Protection Agency, Dublin	Dublin 14
312T	Independent Milk Laboratory Limited	Co. Cavan
6011	Stellar Certification Services Ltd	Dublin 3

For further information, please refer to the Directory of Accredited Bodies.

GLOSSARY OF TERMS

AB	Accreditation Body
EA	European Co-operation for Accreditation
IAF	International Accreditation Forum
ILAC	International Laboratory Accreditation Co-operation
PT	Proficiency Testing

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The INAB Standard is published bi annually and is available on www.inab.ie

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