



30 YEARS OF ACCREDITATION IN IRELAND

A message from the INAB Manager

The Irish National Accreditation Board (INAB), was established in 1985 to provide accreditation of testing and calibration laboratories. 30 years later, a lot has changed and accreditation continues to grow and support Irish enterprise and public policy.

History in the Public Sector

INAB was part of the National Standards Authority of Ireland (NSAI). As INAB grew and extended its services into the accreditation of certification bodies, the 2 bodies were separated and INAB became a division of Forfás, the National Policy and Advisory Board for Enterprise, Trade, Science, Technology and Innovation. In August 2014, INAB became part of the Health and Safety Authority. During these re-organisational changes, INAB has remained under the auspices of the Department of Enterprise, Jobs and Innovation.

Growth in INAB's Responsibilities

From its inception, INAB has accredited laboratories to ISO 17025. From 1994, our mandate extended to the accreditation of certification bodies. Our programme now covers all international accreditation standards which have emerged over 30 years.

In 1991, INAB was given statutory responsibility for the enforcement of the Good Laboratory Practice Regulations (GLP). In 1994, INAB was designated as the competent body under the European Commission Eco-Audit and Management Scheme (EMAS).

The most significant piece of legislation governing the operation of accreditation in Europe was implemented in 2010 when INAB was appointed as the sole national accreditation body for Ireland under Regulation 765/2008.

Name Changes & Branding

On establishment, INAB was named the Irish Laboratory Accreditation Board (ILAB). In 1994, the name changed to NAB and in early 2003 NAB was renamed INAB, The Irish National Accreditation Board.

Our accreditation symbol also changed over time and the current 'tick and harp' symbol was introduced in 2003 to coincide with the final name change and is trademark protected. This symbol is used by all clients to promote and identify their accredited status.



Our Accreditation Symbol introduced in 2003

International Recognition

INAB is an internationally recognised accreditation body. This international recognition is provided for through a series of recognition agreements both on the European and international level.

Associations of accreditation bodies are established in Europe as EA – the European Co-Operation for Accreditation and worldwide as ILAC – the International Laboratory Accreditation Co-Operation and IAF – the International Accreditation Forum.

Accreditation bodies are evaluated periodically to determine their compliance to ISO 17011 and Regulation 765/2008. Following successful evaluations the AB can sign the recognition agreements, known as multi-lateral agreements (MLAs). The benefit of these agreements means that INAB accredited client's certificates & reports are recognised internationally and this avoids the necessity for duplicate testing or certification of traded goods and services.

The following table presents the dates where INAB has grown its MLA and international status.

Standard/MLA	EA Signatory Date	ILAC Signatory Date	IAF Signatory Date
ISO 17025	17/06/1993	02/11/2000	n/a
ISO 15189	05/10/2006	02/11/2000	n/a
ISO 17020	05/10/2006	24/10/2012	n/a
ISO 17021	23/06/1998	n/a	29/10/1999
ISO 17065	15/10/2002	n/a	09/10/2004
ISO 14065	03/10/2014	n/a	n/a

The Future

Today INAB has over 210 accredited clients covering a wide range of activities and demand continues to grow. Our accredited clients offer services in the food, environmental, engineering and construction sectors, supporting enterprise and facilitating trade of Irish goods and services. Accredited pathology testing is contributing to improved patient care while accredited inspection bodies are inspecting products for essential safety requirements.

A large portion of accredited activity now supports European and national legislation and public policy – examples include food and water safety, air emissions, animal health and blood transfusion testing.

I have every reason to expect that the demand for accreditation will grow over coming years and INAB looks forward to continuing and expanding our role to meet that demand.



**MERRY CHRISTMAS
FROM INAB**



INAB would like to wish all our clients, assessors and board members a very happy Christmas and prosperous New Year.

DEVELOPMENTS IN INAB

LAUNCH OF SHAREFILE

INAB are delighted to announce that 'ShareFile' was launched in November 2015. The ShareFile system temporarily stores required documents for the assessment process which Assessors and INAB Staff can access. This eliminates the step of organisations preparing paper packs and sending them to INAB, and INAB forwarding these to the relevant team members. Issues with attachments and email size are also avoided and all relevant information is immediately accessible to the team.

Each organisation has its own secure folder, which is accessible to the organisation and the assessment team assigned to a particular visit set up by INAB.

The organisation accesses the folder via logging into a unique account using a username and password. Organisations then upload the relevant documents (PS10/Corrective actions) for each visit.

The Assessor/INAB officer can then access the documents for download.

The software was piloted in January 2015 and the feedback was positive. The system is easy to use and there is an App available for convenient use with iPhone/iPad or android mobile technology. For more general information and information on software security please visit www.sharefile.com

IS20 and IS21 Guidelines for Organisations and Assessors using ShareFile describes further how to use the system and are available on www.inab.ie



FLEXIBLE SCOPE ROLL-OUT 2016

In response to client feedback, INAB has developed a policy statement for laboratories wishing to apply for a flexible scope of accreditation.

The policy defines the INAB process in place to allow laboratories to report as accredited, results of tests not currently listed in their scope of accreditation.

A flexible scope has been available for ISO 17025 Chemistry testing laboratories for many years and it has now been expanded to cater for all testing laboratories including ISO 15189.

The revised policy statement has been approved in principle by the INAB board and we are now progressing to the pilot stage of implementation.

The Bons Secours Health System (Cork) and the Rotunda Hospital are participating in the pilot which are taking place in Q4 2015 and Q1 2016.

Representatives from both of these laboratories have been involved in the development of the policy document over the course of 2015.

It is expected that INAB will be in a position to accept applicants from for all testing laboratories wishing to avail of this system from the end of Q1 2016.

TRANSITION PLANS

INAB have developed and rolled out plans for transition to ISO 9001 and ISO 14001; ISO 50003:2014 and ISO TS 22003:2013.

All plans are available on www.inab.ie in the notifications section under Documents and Forms. Clients should ensure they know the timeframes and requirements.

Please contact your Accreditation Officer for further information.

NEW POLICY ON MINIMUM VERIFICATION REQUIREMENTS

INAB receives frequent feedback from its clients seeking guidance on minimum requirements of verification of test methods.

In response to this feedback INAB has developed a new policy statement defining the minimum requirements expected from laboratories in their documentation of verifications completed. This will hopefully improve the consistency of INAB assessment process and also allow for the consistent application of the requirements for all testing laboratories. The new policy statement will apply to both ISO 17025 and ISO 15189 testing laboratories.

To clarify, the term Verification is used to describe how a laboratory demonstrates that a validated method/kit/reagent/equipment, used without modification, can be satisfactorily performed by the user, to meet defined criteria and end user requirements. This is distinctly different from

Validation which is the term used to describe how a laboratory develops a new method, develops its own in house methods, uses new technology and introduces other significant modifications in its operations. The new policy statement on Verification requirements defines the minimum requirements the laboratory must address in the following areas:

1. Verification plan.
2. Verification report.
3. Implementation of the verified process in the overall laboratory quality system.

The policy document underwent a consultation process, and was officially approved at the INAB Board. It will be available for all laboratories from January 2016.

INAB MARK FIRST ANNIVERSARY IN HEALTH AND SAFETY AUTHORITY (HSA)

It is hard to believe that 1 year has passed since INAB and its operations moved to Dublin 1 and became part of the Health and Safety Authority (HSA) in September 2014. INAB would like to extend our thanks to our clients, assessors and our colleagues in the HSA for their support over the year.

INAB HOST TWO INTERNATIONAL MEETINGS

The meeting of the Environment Working Group of the EA (European Co-operation for Accreditation) Certification Committee took place on 21st October. Delegates included members of accreditation bodies and stakeholders and Mr Michael Berger, Deputy Secretary General of PEFC International (Programme for the Endorsement of Forest Certification), was also in attendance.

Topics discussed included: End of Waste regulations, ISO 14001:2015, PEFC), Energy Management and BREEAM (Building Research Establishment Environmental Assessment Methodology).

The open and closed meetings of the Forum of Accreditation and Licensing Bodies (established under the EMAS Regulation 1221/2009) took place on the 22nd and 23rd October. Among the topics discussed were: Sectoral Reference Documents; ISO 14001 revision and impact on EMAS; Conference celebrating 20 years of EMAS.

At the closed meeting peer evaluation reports are presented and among those reviewed and discussed was the peer evaluation of INAB that was conducted in December 2014. INAB's continuation as an accreditation body for the EMAS scheme was confirmed.

The European Commission's Eco Management and Audit Scheme (EMAS) is outlined in the Council Regulation No. EC/1221/2009.

INAB is the designated competent body for EMAS in Ireland. As competent body, INAB has responsibility to inform the European Commission of all organisations registered in Ireland and also maintains this register of EMAS sites in Ireland.

A link to a video promoting EMAS is available for viewing on our website.

<http://www.inab.ie/About-Accreditation/Accreditation-Schemes/European-Eco-Management-and-Audit-Scheme-EMAS/>



PUBLIC HEALTH LABORATORY AWARDED ISO 15189 ACCREDITATION

On 9th June 2015, the Public Health Laboratory, Health Service Executive (Dublin Mid Leinster), was accredited by INAB to undertake microbiological testing of clinical samples in compliance with the International Standard ISO 15189:2012.



(L-R): Ms Mary Linehan, PHL Chief Medical Scientist; Ms Ita Kinahan, INAB Board Member; Ms Lucy Devlin, PHL Quality Systems Manager; Dr Eleanor McNamara, PHL Consultant Microbiologist; and Ms Alva Byrne, HSE Dublin Mid Leinster Area Management.

L.I.P. DIAGNOSTIC SERVICES FANNIN LTD AWARDED ISO 17025 ACCREDITATION

On 9th June 2015, Fannin Ltd was accredited by INAB to the International Standard ISO 17025 for their Biological Testing laboratory.



(L-R): Eva Lyons, QA Manager; Irene Slevin, ECA Manager; Marian Quigney, Lab/Technical Manager; Claire Lynch, Deputy Lab Manager – Fannin Ltd; and Dr Adrienne Duff, INAB Manager.

HSA BOARD APPOINT NEW INAB BOARD MEMBERS

Mr Grant Henderson, Applus and Dr Micheál Lehane, Environmental Protection Agency (EPA) were recently appointed by the Health and Safety Authority (HSA) Board.

Other changes on the board included the reappointment of the chair Mr Tom O'Neill, for his final year as he will be on the board 10 years in 2016. INAB and the board would like to extend our thanks to Dr Nuala Bannon, who retired from her position following a 10 year term.

The full INAB board membership can be viewed in full on www.inab.ie



Grant Henderson
Country Manager, Ireland and UK
Applus Car Testing Service Ltd

Grant's role for the past 6 years has been managing director of Applus Ireland. Applus is one of the world's leading companies in testing, inspection and certification working in both the public and private sectors. It provides solutions for customers in all types of industries to ensure their assets and products meet quality, health & safety and environmental standards and regulations.

In Ireland, the focus for Applus is road safety and we provided a number of test and inspection services to government agencies that include vehicle suitability and road worthiness testing, driver testing and enforcement as well as road safety education.

As a certifying body, accreditation is a key demonstrable measure of our professionalism, integrity and our ability. Since 2012 Applus has successfully attained the following certifications, ISO 14001 for environmental, ISO 9001 for quality, OHSAS 18001 for occupational health and safety and accreditation for ISO 17020 Inspection standard.

Prior to working for Applus in Ireland, Grant spent 20 years in the business support services industry in the UK and as senior director of operations with Amey was responsible for the operational delivery of a wide range of business and facilities support services into the transport, health and education sectors as well as local government across the UK.

Grant is 55, married to Sarah and has three grown up children. His main interests are travel, cooking and hill walking. He is a keen follower of rugby and has been known to pull the Irish shirt over his Scottish one in recent years!



Dr Micheál Lehane
Project Manager
Environmental Protection Agency

Dr Micheál Lehane is a Programme Manager with the Environmental Protection Agency. He has over 25 years' experience in environmental protection and management in both the UK and Ireland.

His current role involves the strategic and operational leadership of professional, technical and support staff to deliver the environmental assessment and reporting functions of the EPA. This portfolio of responsibility includes strategic environmental assessment, air quality, bathing water, environmental monitoring and laboratory analytical services and environmental reporting. In this role he has led the transformational change programme for the EPA laboratories to deliver a fully integrated and streamlined service, including the achievement of a single multi-site ISO17025 accreditation for its air and water laboratories.

Micheál is the National Focal Point in Ireland for the European Environment Agency and is the lead author and editor of the EPA flagship State of Environment reports, which assess the environment in the broader socio-economic and health contexts. He also heads the strategy and change management team in the EPA and is currently leading the development of the EPA's new organisational strategy.

Micheál has previously held senior leadership roles in the EPA including communications, governance and environmental research.

Micheál holds a BSc and a PhD from University College Cork, an MBA from the University of Limerick and a Diploma in Management Information Systems from the Irish Management Institute.

INAB ASSESSOR FORUM – JANUARY 2016

INAB will hold its 6th Assessor Forum on 27th January 2016 in Dublin. This forum aims to harmonise the INAB accreditation process and keep assessors up to date with changes in policy and processes. The event takes place every two years.

ISO 15189 SPECIAL EDITION NEWSLETTER

On 22nd October 2015, INAB rolled out a special electronic edition newsletter for our ISO 15189 clients. This edition was part of an overall communications campaign run in 2015 for this sector. It was emailed to all main ISO 15189 client contacts, assessors, the INAB board and membership of the medical advisory committee.



ROYAL COLLEGE OF SURGEONS (RCSI) AWARDED ACCREDITATION TO ISO 15189

On 14th April 2015, the RCSI Pathology Department was accredited to ISO 15189 by the Irish National Accreditation Board.



(L-R): Prof Cathal Kelly, RCSI CEO; Prof Elaine Kay, Consultant Histopathologist, Dept of Pathology; Mr Barry McGowan, Senior Financial Accountant; Dr Adrienne Duff, Manager, INAB; Dr Tony O'Grady, Chief Medical Scientist, Dept of Pathology; Ms Jennifer Cullinane, Director of Finance

LEARNING FROM OUR CLIENTS AND STAKEHOLDERS

When it comes to learning about INABs client base, sourcing feedback and input there is rarely anything more effective than a survey. These surveys give our clients, assessors, and stakeholders a chance to voice their opinion and provide input into INAB and accreditation. INAB carried out a number of surveys in 2015.

HSA Strategy 2016-2018 – Survey

In March 2016, INAB surveyed its clients, stakeholders, board and regulators, for input into the HSA Strategy for 2016-2018 process on INAB activity. Public consultation was also open and responded too. The final version of the strategy was recently agreed at the September HSA Board. It was submitted to the Minister of State at the Department of Jobs, Enterprise and Innovation for consideration and on approval will be launched by the Minister in the New Year.

Experience of INAB Service and Communications – Assessor Survey

On the 28th July 2015, all INAB active assessors were invited to participate in a survey on their experience of INAB service and communications. The survey looked for feedback on:

- Communications – updates and how they are delivered.
- INAB Assessor Forum – feedback and contribution to 2016.
- INAB Processes – information and training.
- Billing and Invoicing – experience.

Overall, 33% (45) of our active assessors completed the survey.

The survey will assist INAB with planning and delivering training to support our assessors and harmonise the accreditation process. It has also contributed to the planning of the Assessor Forum in 2016.

INAB Medical Client Information Day – Feedback

In July 2015, following INABs Medical Client Information day a survey was conducted for feedback on the day, content and speakers. Overall it was a very positive response with participants advising that they would welcome more such events. Results were published in the special edition ISO 15189 newsletter rolled out in October.

Medical Advisory Committee

Work Plan 2016 – 2018

In October, our ISO 15189 clients were invited to complete a survey to provide technical issues and identify areas where further technical guidance is required on the interpretation of specific requirements for accreditation.

Responses once collated would be considered for inclusion in the 2016-2018 MAC work plan. This survey link was included in the ISO 15189 special edition newsletter.

INAB would like to extend our thanks to all that have contributed and participated in our surveys from 2015.

FEES HELD FOR 2016

INAB are pleased to announce that fees will remain unchanged. Please note that schedules apply for work carried out in Ireland. The INAB Schedule of Fees for 2016 will be available from our website in January 2016. Please contact your INAB officer if you have any queries.

WE WANT YOUR FEEDBACK

Feedback provides INAB with the opportunity to learn and improve our processes. We value all feedback and recognize the importance of client and assessor feedback into the INAB system and processes. INAB is committed to providing a professional service and as such have a variety of documents which describe the accreditation process. These include; Guide to INAB Assessment Procedures, Code of Conduct for Assessment Teams and the R1 regulations all available on www.inab.ie

These documents describe many important aspects of how the INAB Accreditation process operates.

How Can You Provide Feedback?

Feedback Forms

The client feedback form is available on www.inab.ie and can be found in the "contact us" section.

This form caters for improvements, suggestions and feedback you may have relating to INAB policy, assessment visits, or any aspect of the accreditation process.

The assessor feedback form can be found on Sharefile.

Forms should be returned to inab@inab.ie and will be reviewed for action by the INAB Executive.

INAB Policy for Handling Complaints

Complaints made to INAB shall be addressed in writing to the INAB Manager. The regulations for handling complaints can be found in the INAB R1 Regulations, Section 7 on page 20. This document is available on our website in the "Documents and Forms" section.

Complaints about our Accredited Bodies should be directed to the accredited body in the first instance.

Surveys

INAB conduct surveys frequently – see page 5 for those carried out in 2015.

General Queries

All general queries can be directed to our email address: inab@inab.ie

GLOSSARY OF TERMS

CABS	Conformity Assessment Bodies
EA	European Co-operation for Accreditation
EA MLA	European Co-operation for Accreditation Multi-lateral Agreements
IAF	International Accreditation Forum
ILAC	International Laboratory Accreditation Co-operation

ACCREDITATIONS AWARDED TO NOVEMBER 2015

330MT	The Adelaide & Meath Incorporating The National Children's Hospital	Dublin 24
313MT	Royal College Surgeons in Ireland	Dublin 9
332T	L.I.P. Diagnostic Services, Fannin Ltd.	Co. Galway
333MT	Cork University Hospital, Laboratory Medicine	Co. Cork
334MT	Public Health Laboratory, HSE Dublin Mid Leinster	Dublin 10
335T	Agri Diagnostics Ireland Ltd.	Co. Kerry
336T	Dairygold Food Ingredients Ltd.	Co. Cork
337T	Kildeen Enterprises T/A Medical Consultants Pathology Group	Dublin

For further information, please refer to the Directory of Accredited Bodies available on www.inab.ie

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

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