



MERRY CHRISTMAS FROM INAB

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



CEO WELCOMES INAB TO THE HEALTH AND SAFETY AUTHORITY



I would sincerely like to again welcome the staff of INAB to the Health and Safety Authority. You will know that, following a decision by Minister Bruton in 2011, the staff and functions of the Irish National Accreditation Board were integrated into the Authority on 1st August 2014, on the dissolution of Forfás.

The 2014 Act (Industrial Development [Dissolution of Forfás]) which amended the Health, Safety and Work Act 2005, copper-fastened this integration ensuring a sound legislative footing for all INAB activity. Thanks to the close co-operation and planning of the staff of the Authority, Forfás and INAB, integration occurred with continuity of service to INAB clients.

The Authority and INAB have enjoyed a long working relationship prior to this integration, in the areas of: asbestos monitoring, transport of dangerous goods by road (ADR Regulations), GLP as part of the REACH legislation and the accreditation of notified bodies.

I am committed to working with INAB to ensure a continued level of service excellence and continuous improvement based on client feedback.

With best wishes

Martin O'Halloran
CEO



SCHEDULE OF FEES 2015

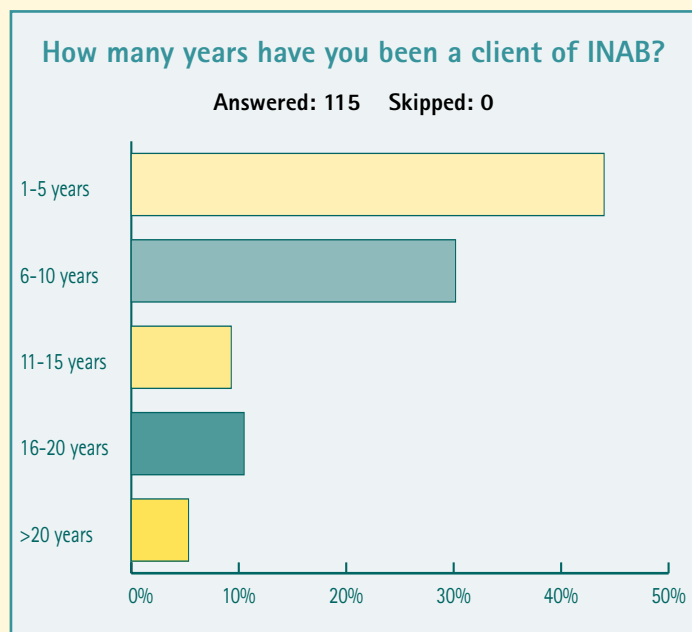
For 2015, INAB are pleased to announce that the fees will remain unchanged. Please note that schedules apply for work carried out in Ireland. Please contact your INAB Accreditation Officer if you have any queries. The INAB Schedule of Fees will be available from the INAB website www.inab.ie from January 2015.

INAB CLIENT SATISFACTION SURVEY 2014

INAB distributed an online survey via email to all its accredited and applicant members in May 2014. The main objective of the survey was to ascertain our member's satisfaction with the accreditation process and service. All recipients were asked to complete the survey by the end of June 2014.

Review of Respondents

- 115 clients responded to the survey.
- 44% are clients for the ISO 15189 – Medical Testing Scheme.
- 53% – ISO 17025 – Testing and Calibration.
- 6% represent Certification/Inspection.



Personnel and Service Handling

- 83% agreed INAB is easy to contact.
- 86% agreed staff are professional.
- 73% agreed INAB staff respond in a timely manner.

Application Stage

- 69% agreed sufficient information available from INAB and website.
- 65% agreed INAB was efficient at processing application.

INAB Assessment Visit

- 92% agreed purpose and nature of visit was clearly explained.
- 83% agreed visit arrangements handled efficiently and effectively.

INAB Assessment Team

- 93% agreed assessment team assessed their competence for a specific range of activities.
- 90% agreed assessment team communicated in a controlled and professional manner.
- 78% agreed the assessment team understood their business.
- 70% agreed the assessment team resolved their concerns on the day of the visit.
- 88% agreed findings were presented in a calm manner.

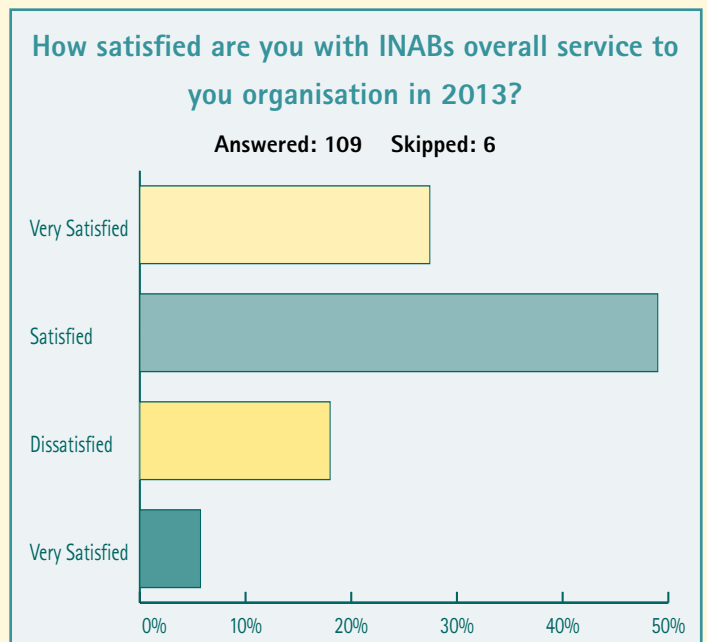
- 86% agreed assessor demonstrated current competence in the activity being assessed.
- 81% agreed assessment team adhered to the PS8 – Code of Conduct.

Post Visit

- 63% agreed INAB dealt with post visit queries satisfactorily (before submission of corrective actions).
- 68% agreed assessment team handled correction actions promptly.
- 77% agreed assessment team communicated any issues clearly.
- 77% agreed the decision on their accreditation was promptly relayed.
- 56% agreed revised scope applications were processed in a timely manner.
- 54% agreed extension to scope applications are processed in a timely manner.

Value

- 73% agreed findings added value and contributed to improvements.
- 83% agreed accreditation brings value to their business.
- 96% agreed achieving accreditation with INAB is a significant accomplishment.
- 51% agreed membership is money well spent.
- 49% agreed INAB regards them as a valued client.
- 68% agreed INAB promotes their accreditation appropriately on website, newsletter and press.



The results were presented to the INAB Executive in October and an action plan will be prepared and presented to the INAB Board.

We very much welcome your feedback and would like to thank all our members that kindly participated in the survey.

Clients that would like to provide further feedback can complete the Client Feedback form available on our website under the:

Contact Us section <http://inab.ie/Contact-Us/Client-Feedback-Form/>

INAB EXTEND IAF MULTI-LATERAL AGREEMENT TO INCLUDE GLOBALG.A.P. LEVEL 4 & 5

On the 16th October, Dr Adrienne Duff, Manager of INAB accepted the IAF MLA multi-lateral agreement certificate from Randy Dougherty, IAF Chairman, at the IAF/ILAC Joint Annual Meeting in Vancouver.

This certificate outlines the extension of INABs multi-lateral agreement to include the sub-scopes:

- Level 4: GLOBALG.A.P. General Regulations, and
- Level 5: GLOBALG.A.P. Integrated Farm Assurance Control Points and Compliance Criteria.

INAB is a signatory to the IAF multi-lateral agreement (MLA) on product certification; IAF is a signatory to the MoU with FoodPLUS GmbH for accreditation of certification bodies involved in GLOBALG.A.P. certification activities.

G.A.P. stands for Good Agricultural Practice – and GLOBALG.A.P. is the worldwide standard that assures it. It is a global organisation with a crucial objective: safe, sustainable agriculture worldwide.

INAB currently has one certification body accredited that include GLOBALG.A.P. on their scope.

- Bord Bia Quality Assurance Board – Dublin.

For a full list of signatories to this MLA, see:
http://www.globalgap.org/uk_en/



Randy Dougherty, Chairman, International Accreditation Forum, Inc. presents IAF multi-lateral agreement certificate to Dr Adrienne Duff, Manager, INAB.

INAB EXTEND SCOPE TO INCLUDE VERIFICATION

INAB have successfully undergone peer evaluation by European Co-operation for Accreditation (EA) for accreditation of verifiers as required by Article 64 of Commission Regulation (EU) No 600/2012.

INAB officially signed the agreement during the EA General Assembly held in The Hague, the Netherlands on 19th-20th November 2014.

NEW ILAC WEBSITE



The International Laboratory Accreditation Cooperation (ILAC) launched its new website at the end of August. The new website will play an important role in the organisation's relationship with its members and stakeholders.

The website includes several new features that improve the availability of information, such as:

- A dedicated search for the signatories to the ILAC MRA.
- Consolidation of the information on the signatories to the ILAC MRA to one page.
- A specific area for regulators and users of the ILAC MRA.
- Link to the directories of accredited proficiency testing providers and reference material producers, where available, in addition to the current links to accredited laboratories and inspection bodies.

The ILAC Signatory search is now available from the INAB website. This is a dedicated search for the signatories to the ILAC multi-lateral arrangement.



MEDICAL ADVISORY COMMITTEE

In 2010, INAB established the Medical Advisory Committee (MAC), its purpose to offer advice to the INAB Executive on issues of principal importance in accreditation to ISO 15189.

The committee has been meeting for four years and is chaired by Dr Cor de Ruiter, lead assessor and former operational manager from the Dutch Accreditation Council (RvA). The membership includes a wide spectrum of medical expertise from all relevant disciplines and end users of accreditation.

INAB would like to welcome Dr Gerard Boran, Clinical Chemistry Department, AMNCH representing the National POCT Consultative Group and Mr Chris Sharpe, Lead and Technical Assessor for four European Accreditation Bodies, Former Laboratory and Quality Manager for a University Hospital Trust in the UK.

MAC Task Force Groups

There are currently a number of active task force groups on the Medical Advisory Committee, with the recent addition of POCT, Point of Care Testing; and the molecular diagnostics group which will be led by Patrick Hayden with Dr Aileen Butler, Principal Clinical Molecular Geneticist at Our Lady's Children Hospital, Crumlin.

Haematology/Blood Transfusion	Patrick Hayden John O'Loughlin Emma Scott McGrane
Clinical/Chemistry/POCT	Mike Louw Gerard Boran Emma Scott McGrane
Immunology	Vincent Tormey Marie O'Mahony
Microbiology	Chris Sharpe Sinead Guckian
Histopathology	Michael McDermott Brid Burke
Molecular Diagnostics	Patrick Hayden Aileen Butler Marie O'Mahony

Members are appointed based on their competence and experience to deal with specific issues or queries related to medical laboratory accreditation.

The MAC met on 21st October 2014. Items on the agenda included:

- FAQ MAC working document on ISO 15189:2012 which will be presented to the INAB Board in December 2015.
- The Chair presented a new procedure for the functioning of Task Force Groups within the MAC which was welcomed by the committee.
- INAB sought MAC input on validation/verification procedures; the committee agreed that each task force group would produce recommendations containing minimum criteria for use by laboratories for validation/verification for each discipline by our next meeting in March 2015.
- Presentations by INAB on new policy PS23 and revisions to Notification on sample handling.

Current Membership of the MAC

CHAIRPERSON: Dr Cor de Ruiter

Lead assessor and former operational manager from the Dutch Accreditation Council (RvA)

Ms Sinead Guckian, Ms Marie O'Mahony, Ms Brid Burke, Dr Emma Scott McGrane

Accreditation Officers, 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

Mr John O'Loughlin

Laboratory Manager, Rotunda Hospital

Ms Denise O'Neill

Pathology Quality Manager, Mater Misericordiae University Hospital

Dr Vincent Tormey

Consultant Immunologist, Galway University College Hospital

Dr Mike Louw

Consultant Clinical Chemist, Claymon Biomnis Laboratories Ltd

Mr Chris Sharpe

Lead and Technical Assessor for four European Accreditation Bodies; Former Laboratory and Quality Manager for a University Hospital Trust in UK

Dr Sean Cunningham

Joint Working Group on Accreditation

Dr Gerard Boran

Representing POCT Consultative Group

INAB would like to extend our thanks to all members for their continued work and commitment to INAB.

The MAC will meet in 2015 on 30th March and 19th October.

PROMOTING INAB APPROACH TO ISO 15189:2012

In September and October, Accreditation, specifically the medical standard ISO 15189:2012 was included on the agendas of the following meetings. INAB staff presented and answered questions on the day.

- Irish Molecular Diagnostics Network Meeting on 26th September – Adrienne Duff, INAB Manager.
- IEQAS Annual Conference on 2nd October – Adrienne Duff, INAB Manager.
- Roche user group meeting on 15th October – Brid Burke, INAB Accreditation Officer.

CHANGES ON THE INAB BOARD

New Appointments

INAB would like to welcome our newest members.



Raymond Ellard
Director of Consumer Protection
Food Safety Authority Ireland

Raymond Ellard is the Director of Consumer Protection at the Food Safety Authority of Ireland. He has worked in various aspects of food control from the local to the international level since he qualified as environmental health officer (EHO) in Ireland in 1975. For eight years he was Chief Environmental Health Officer with the Department of Health and Children. He moved to the then newly established Food Safety Authority of Ireland (FSAI) as Chief Specialist in Environmental Health, before taking up his present post there as one of the Directors.

Currently, as the Director of Consumer Protection, he is responsible for the Authority's training group, veterinary public health group, food incident team, data collection and the Consultative Council.

He has worked with the EU systems as a national expert representing Ireland at various working groups on food safety and food regulation. He worked internationally as a consultant on food control for both the World Health Organization and the Food and Agriculture Organisation. In addition he worked as a training provider and project leader on food safety and food control for many EU candidate countries. He represents FSAI at the European Food Safety Authority's (EFSA) Advisory Forum and was chair of EFSA's Working Group on Crisis Preparedness.

For five years from 2006 he was Honorary Secretary of the International Federation of Environmental Health. He holds three Master's Degrees – one each in Food Science, Health Services Management and European Food Regulatory Affairs.



Peter Dennehy
Director of Corporate Services, Deputy CEO and Board Secretary
The Nursing & Midwifery Board of Ireland (NMBI)

Peter Dennehy, as well as being the Director of Corporate Services, is Deputy CEO and Board Secretary at the NMBI.

Spanning 30 years, Peter has held Senior Manager positions in the Public, Private and International sectors, he is an experienced leader of Irish, UK and Worldwide organisations within technology, services, international standards and government regulatory organisations.

Peter is a graduate of Trinity College Dublin University, a Chartered Engineer, a Fellow of the Institute of Engineers Ireland and a Member of the Institute of Directors.

In 2006, Peter was appointed as Director of the Road Safety Authority a position he held for five years.

In 2002, Peter was Head of Conformity Assessment at the International Organisation for Standardisation (ISO) and Secretary to ISO/CASCO. For two years Peter had the privilege of leading an exceptional team of ISO Central Secretariat staff and International Experts from 156 countries, in the development, revision and promulgation of the ISO's and IEC's family of International Conformity Assessment Standards.

RESIGNATIONS

Martin O'Halloran (HSA); John Shine, National Consumer Agency; and Prof Alan Reilly, Food Safety Authority Ireland resigned from the Board in 2014. The INAB Board and Executive would like to sincerely thank our retiring members for their significant contribution to INAB.

The INAB Board have six meetings planned for 2015. Its first meeting will take place on February 24th 2015.

INAB POLICY REVIEW AND AMENDMENTS

New Policy – PS23

PS23 sets out INAB Policy for both ISO/IEC 17025 testing and calibration laboratories and ISO 15189 medical testing laboratories when they are offering accredited testing/calibration services. If a laboratory is accredited for a test/calibration as defined in the laboratory's scope of accreditation, then the laboratory shall offer this test/calibration as an accredited service at all times.

In the case of medical laboratories INAB recognises and acknowledges that these laboratories may offer a reduced suite of tests (for example during out of hours or at weekends), however for this reduced suite of tests the laboratory is required to provide the same level of accredited testing service whenever the testing is being undertaken.

Notification on sample-handling, processing and timely reporting of critical samples as per ISO 15189 requirements

This notification is a revision to the initial INAB notification on Blood Cultures issued to applicant and accredited medical testing laboratories in March 2014 and has been revised to incorporate comments and feedback obtained by INAB from a number of sources, including The Irish Society of Clinical Microbiologists, the INAB Medical Advisory committee (MAC) and the EA WG (European Accreditation Working Group) on Healthcare.

The key changes to the original notification are as follows:

- A change of the title to more accurately reflect the purpose of the notification which is related to sample handling, processing and timely reporting of critical samples as per ISO 15189 requirements.
- The notification now allows for the clinician responsible for the patient, and not the consultant microbiologist, to be informed in the event of an urgent positive result.
- The section on ISO 15189 examination procedures clause 5.5.1 stating that preferred procedures are international, national or regional guidelines has been removed as it was confusing the issue and was not central to the notification on handling and reporting of urgent samples and results in a timely manner.

Please note the three month timeframe statement in this notification (Section 4) has been removed as that applied to the March 2014 notification date and is not applicable for this revision.

Please contact your INAB Officer if you have any further queries.

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

NEW ACCREDITATIONS AWARDED IN 2014

322T	APAC Consulting Ltd t/a Glenside Environmental	Cork
321MT	Sligo Regional Hospital Microbiology Department	Sligo
5011	Management Systems Certification Ltd	Wexford
001RM	Reagecon Diagnostics Ltd	Clare
324T	FarmLab Diagnostics Ltd	Roscommon
323T	Teagasc Food Research Centre	Cork
325MT	Our Lady's Children's Hospital Division of Pathology & Laboratory Medicine	Dublin
326MT	National Virus Reference Laboratory	Dublin
327MT	St James's Hospital Central Pathology Laboratory	Dublin

(List of awards up to October 2014)

A list of extensions to scope awarded in 2014 by the INAB Manager and Board will be available on the INAB website in January 2015.

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

EDITOR

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

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