



TAOISEACH CELEBRATES AIRMIDS INAB ACCREDITATION

Taoiseach Enda Kenny congratulated Dublin based research facility, **airmid healthgroup** on becoming INAB accredited in a biomedical field of indoor air pollution and health. Airmid is the first ISO 17025 accredited laboratory in the World for Cat & House Dust Mite Allergen testing. The presentation took place on November 10th 2011.



(L-R) Máire Fox, Quality Manager, airmid healthgroup; The Taoiseach, Mr Enda Kenny, TD; James Stapelton, INAB; Dr Bruce Mitchell, Executive Chairman, airmid healthgroup; Angela Southey, Technical Manager, airmid healthgroup.

ACCREDITATION UNVEILED

A plaque records the accreditation details and visit from The Taoiseach.



(L-R) Dr Bruce Mitchell, Executive Chairman, airmid healthgroup; The Taoiseach Enda Kenny TD.

Founded in 2007, airmid healthgroup established as an analytical and test facility for certification body Allergy Standards Ltd, whose clients include leading International asthma & allergy groups, such as the Asthma and Allergy Foundation of America, the Asthma Society of Canada and Asthma UK.

Clients of these certification programmes comprise of world leading manufacturers such as Valspar, LG and Dyson, with products in Lowes, Costco and Wal-Mart.

"airmid healthgroup reflects the huge achievements of Ireland in the area of life sciences, and in biomedical research in particular. Ireland is now in the top 20 in the world for the quality and relevance of our scientific research and due to the efforts of companies like airmid, we are now the number one location in Europe for life sciences projects. And this strength is reflected in terms of multinational investment, exports and jobs"



MERRY CHRISTMAS FROM INAB

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



CHANGES ON THE INAB BOARD

James Stapleton – Secretary to the INAB Board

NEW APPOINTMENTS

On 21st July the Forfás Board approved the appointment of two new members to the INAB Board.



*Mr Jan van der Poel
Dutch Accreditation Council,
RvA*



*Mr Paul Hetherington
Manager – National Metrology
Laboratory, NSAI*

Mr Jan van der Poel has been the Chief Executive of the Dutch Accreditation Council, RvA, since 2002 and is also a member of the Executive Committee of European Cooperation for Accreditation (EA).

Mr Paul Hetherington is the Manager of the National Metrology Laboratory, National Standards Authority of Ireland (NSAI), a position he has held since 1991. He is a member of the NSAI Executive Committee and he has previously served as EURAMET (European Association of National Metrology Institutes) Chairman and is currently on the EURAMET Board of Directors.

At the same meeting the Forfás Board also approved the appointment of current Board member Mr John Shine as Deputy Chairperson to the INAB Board. Mr Shine is the Director of Commercial Practices in the National Consumer Agency.

RETIREMENTS

INAB Board members Mr Michael Maloney and Mr Vagn Andersen retired from the Board in June 2011.

Mr Maloney, Director of Quality at Board Bia and Mr Vagn Andersen, Manager International Affairs at the Danish Accreditation Body (DANAK), had served on the INAB Board since 2001 and 2005 respectively. The INAB Board and Executive would like to sincerely thank our retiring members for their significant contribution to INAB.

SUCCESSFUL OECD GLP RE-EVALUATION OF INAB

INAB had its second OECD re-evaluation of the National Good Laboratory Practice GLP Compliance Monitoring Programme in October 2011. The purpose of the re-evaluation is to provide continued assurance that INAB continues to operate effectively as the National GLP Compliance Monitoring Authority.

The emphasis of this on-site re-evaluation visit was on the observation by the OECD GLP team of an INAB GLP inspection (and study audits) at a test facility. Two days were also spent in INAB offices reviewing INAB processes, procedures and records for the programme.

INAB is delighted at the successful outcome of the evaluation and would like to thank the OECD team for its professionalism in conducting the evaluation and would also like to thank all the staff at Charles River Laboratories Pre-Clinical Services Ireland Ltd (CRLPSI) for accommodating the OECD team and the INAB GLP inspection team from the 4th-6th October 2011.

The report from the re-evaluation will be presented to the OECD Working Group (WG) on GLP in Paris in 2012. The successful outcome and the positive recommendations from the OECD team will provide continued confidence to the members of the GLP WG (and in turn to the Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology) in INAB's national GLP Compliance programme, thus minimizing the need for individual member monitoring programmes to perform inspections and/or study audits in Ireland.

The Irish National Accreditation Board (INAB) has the statutory responsibility for the European Union and the Organisation for Economic Co-operation and Development (EU/OECD) Good Laboratory practice (GLP) Compliance Monitoring scheme in Ireland.

The Principles of Good Laboratory Practice apply to all non-clinical health and environmental safety studies required by regulations for the purpose of registering or licensing pharmaceuticals, pesticides, food and feed additives, cosmetic products, veterinary drug products and similar products, and for the regulation of industrial chemicals.



Charles River Laboratories staff and INAB Team.

ACCREDITATION OF STACK EMISSION SAMPLING AND TESTING



The Environmental Protection Agency (EPA) requires operators with emission permits (IPPC and Waste licences) to undertake the monitoring of process emissions to ensure they are within the permissible limits. To comply with this requirement, organisations

may either use in-house monitoring services or avail of the services of an external contractor.

Where third party external contractors are used to conduct this monitoring, the EPA has determined that they hold accreditation to ISO/IEC 17025 by January 2014 in association with CEN/TS 15675, for the emission monitoring and testing being performed, for a number of defined test parameters.

The applicable reference standards are:

- CEN/TS 15675:2007-10: *Air quality – Measurement of stationary source emissions – Application of EN ISO/IEC 17025:2005 to periodic measurements.*
- EN 15259:2007-10: *Air quality – Measurement of stationary source emissions – Requirements for measurement sections and sites and for the measurement objective, plan and report.*
- CEN/TS 15674:2007-10: *Air quality – Measurement of stationary source emissions – Guidelines for the elaboration of standardised methods.*
- EPA AG1: *Guidance on Site Safety requirements for Air Emissions Monitoring.*
- EPA AG2: *Air Emissions Monitoring Guidance Note #2.*

Accreditation to ISO/IEC 17025 provides an independent and authoritative declaration that the organisation carrying out the emissions monitoring and testing has the personnel, facilities, equipment, technical expertise, and documented management systems to undertake the activity professionally and competently.

The organisation must demonstrate, for example, that:

- Individuals carrying out emissions monitoring and testing are technically competent to do so and that methods are performed to EPA specifications (AG1 and AG2) and the international standards referenced above.
- Equipment and methods are validated and demonstrated to be fit for purpose.
- Equipment is calibrated to international traceable standards.

- The organisation has robust internal training programmes and carry out routine competence monitoring. That regular internal auditing is performed by qualified auditors.
- That there is regular participation in recognised proficiency testing schemes.
- Work is adequately resourced and any deviations to the work are immediately brought to the attention of the customer.
- The organisation has a complaints process and that it has robust procedures to ensure that it routinely audits its own work and that any areas of concern are investigated and dealt with in a timely and appropriate manner.
- All emissions monitoring work is carried out independently and impartially to ensure that staff are free from undue financial, commercial or other pressures that may adversely affect the quality of work.

The following INAB policies and processes apply to accreditation for stack emission monitoring and testing in addition to all requirements in ISO 17025 and reference standards:

- For accreditation of sampling methods, it is INAB policy to accredit only sampling methods that are published internationally or national standards or those specified in European Directives or Regulations and only when the output of the sampling is subject to testing undertaken by its own accredited laboratory or an accredited subcontracted laboratory. Furthermore, it is INAB policy not to accredit in-house developed sampling methods or any in-house variation of a standard method (INAB Policy Statement PS17 refers).
- The contractor shall partake and achieve satisfactory performance in proficiency testing schemes applicable to the scope of accreditation (INAB Policy Statement PS1 refers). A PT scheme provides a way of assessing the performance of laboratories by a series of regular inter-laboratory comparisons. Proficiency testing schemes are used by accreditation bodies as part of the process to assess the ability of laboratories to competently perform tests and measurements for which accreditation is held. For this scheme, the following minimum proficiency testing requirements apply:
 - Stack emission monitoring such as that provided by the National Physical Laboratory in the UK. INAB has determined that demonstration of satisfactory performance in this scheme is required prior to initial assessment and prior to re-assessment (participation and successful performance once within the 5 year accreditation cycle). Details may found at <http://www.npl.co.uk/environmental-measurement/products-and-services/stack-proficiency-testing-scheme>
 - Particulate proficiency testing scheme – annual participation.
 - Gas calibration proficiency scheme – annual participation.



- The air contractor shall apply to INAB following the process and with reference to AF-1-A application form (new applicants) or AF-2-A for existing INAB accredited clients.
- INAB strongly recommends a pre-assessment visit for all applicants.
- All decisions on award of accreditation for this scheme shall be made by the INAB Board.
- The applicable P9 classification is 781.
- The initial minimum applied for scope should typically include:
 - Total particulates (low & high range).
 - NOX, SO2, CO.
 - VOC (by FID).
 - Gas velocity and temperature.
 - Dioxins.
 - Oxygen.
 - Moisture.

The range of measurement will be determined by the validation performed.

INAB documents and forms are available at www.inab.ie

Further information on air emission monitoring at www.epa.ie

CALIBRATION LABORATORY MAHA IRELAND AWARDED ACCREDITATION

Maha Ireland Ltd was recently presented its Accreditation Certificate by INAB Board member, Tom Dempsey.

The accredited laboratory operates from its headquarters in Rathcoole, Co. Dublin offering a nationwide service for the calibration of vehicle testing equipment.

Appointed by the Road Safety Authority (RSA), the vehicle inspection company, Applus, utilises the calibration service of Maha Ireland Ltd for their NCT centres across the country. Maha Ireland also provides calibration services to many of the Vehicle Testing Network (VTN) organisations.



(L-R) John Mallon, Managing Director, Maha Ireland Limited; Tom Dempsey, INAB Board Member.

MINISTER PRESENTS LENNOX LABORATORIES WITH ITS INAB ACCREDITATION CERTIFICATE

Lennox Laboratories Ltd was accredited to undertake Balance and Temperature Calibration as detailed in their schedule bearing the registration number 288c in compliance with the International Standard ISO/IEC 17025: 2nd edition "General Requirements for the competence of Testing and Calibration Laboratories".

Sean Sherlock, TD, Minister for Research and Innovation presented the award of accreditation to Joe Barry, Managing Director of Lennox Laboratory Supplies Ltd.



(L-R) Derek Dwyer, ISO17025 Deputy Technical Manager; Dermot Hayes, INAB Board Member; Joe Barry, Lennox Managing Director; Sean Sherlock, TD, Minister of State for Research and Innovation; Eilish Browne, Calibration Services Quality Manager; Joe Moran, ISO17025 Technical Manager; Daryl Kingston, Sales Manager; Aodhagan Maunsell & Evan Langan, Calibration Engineers.

INAB ASSESSOR FORUM 2012

INAB are delighted to announce that the 4th INAB Assessor Forum will be held in INAB Offices in Dublin on Friday 20th January 2012.

The forum is held every 2 years – its aim is to harmonise the accreditation process and to give our assessors an opportunity to liaise with other assessors and the INAB Executive in an open forum.

Invitations have been sent out to all active assessors.

Assessors should confirm their attendance by emailing orla.ivers@inab.ie

We look forward to seeing you in Dublin.



INAB MEDICAL ADVISORY COMMITTEE

Cor de Ruiter – Chair of the INAB Medical Advisory Committee

The Medical Advisory Committee (MAC) was established on 9 March 2010 during its first committee meeting. The committee has been established by the Irish National Accreditation Board (INAB), for the sole purpose of offering advice to the INAB Executive on issues of principal importance in medical testing accreditation. The terms of reference of the MAC was approved by the INAB Board.

The members are nominated by interested parties and approved by the INAB Executive for a period of 3 years with the possibility of reappointment. The membership includes representatives of the end users of the accreditation scheme. A dedicated committee site has been established on the INAB extranet, where the composition of the committee is published and the members are invited to provide professional body guidance/mandatory documents and advice on relevant legislation for each discipline.

The committee has a liaison through Dr Emma Scott McGrane and Sinead Guckian who represent INAB at EA level. Since the establishment of the MAC, 5 meetings have been held.

The following achievements and highlights were reported.

- Establishment and execution of a Committee Workplan for 2010-2012.
- The formation of the Task Force Groups (TFG's) for the different medical disciplines that will propose guidance for different areas, e.g. validation of methods, external QA schemes, appropriate level of on-site and off-site advisory services, minimum requirements for Consultant cover/Deputy cover/On-Call cover. Outputs were obtained in 2011.
- Sharing information about the Committee Draft (CD) ISO 15189:20XX and ISO DIS 15189:2011.
- Flexible Scopes for Medical Laboratories, based on:
 - EA-2/15 "EA Requirements for the Accreditation of Flexible Scopes".
 - EA-4/17 "EA Position paper on the description of scopes of accreditation of medical laboratories".
 - INAB Policy Statement PS11, client feedback and output from the TFG's.
 - The MAC advised the INAB Board to revise INAB's Policy Statement PS11 so that medical laboratories could be granted accreditation for a flexible scope in combination with a list of additionally accredited tests (LAAT). This will be finalised in 2012.

Each year the manager of INAB and the chair of the MAC draft an annual report of the MAC to the INAB Board.

INAB ANNUAL MANAGEMENT REVIEW

INAB held its Annual Management Review meeting on 21st November 2011

INABs management review takes place once a year. The review is conducted to an agenda drawn up by the Quality Manager and chaired by the Manager of INAB. Some of the items on the agenda included:

- Quality Management System.
- Appeals, Complaints.
- Staff Training, Staff and equipment resources.
- Fulfilment of objectives.
- Accreditation activities, Standards, and New areas.

Following presentation and discussion a number of actions are raised in order to improve INAB policies, systems and processes and to ensure INAB activities continue to comply with ISO 17011 and best international practice.

The action list from the Management Review is addressed at Divisional meetings.

INAB ACCREDIT FIRST NOTIFIED BODY

Compliance Engineering Ireland Ltd (CEI)
Raystown, Ratoath Road, Ashbourne, Co. Meath

Compliance Engineering became the first notified body awarded accreditation for Inspection of Technical files to determine conformity with EMC Directive (2004/108/EC) and R&TTE Directive (1999/5/EC) at the INAB Board in February 2011.

CEI offers Electromagnetic Compatibility (EMC), radio and electrical safety testing to demonstrate conformity with essential requirements for commercial and automotive markets. CEI is one of Ireland's main approvals providers for electrical and electronic products, operating screened, anechoic and environmental test chambers.



New 10m range Semi Anechoic chamber at CEI – accredited by INAB to perform radio frequency emissions testing.

CEI has also been accredited by INAB as an ISO 17025 testing laboratory since 1998.

ACCREDITATIONS AWARDED IN 2011 BY INAB BOARD

- **Cruinn Diagnostics Ltd t/a CruinnCal, Dublin 12**
Balance & Volumetric and Temperature Calibration Laboratory
- **Cruinn Diagnostics Ltd t/a CruinnCal, Dublin 12**
Mechanical Testing Laboratory
- **Complete Calibrations, Cork**
Mass Calibration Laboratory
- **Compliance Engineering Ireland Ltd, Co. Meath**
Inspection Body
- **airmid healthgroup t/a airmid health laboratory**
Testing Laboratory
- **Mattest (Ireland) Ltd, Dublin**
Testing Laboratory
- **Mattest (Ireland) Ltd, Cork**
Testing Laboratory
- **Maha Ireland Ltd, Co. Dublin**
Calibration Laboratory
- **Laboratory Supplies Ltd.**
t/a Lennox Laboratory Supplies, Dublin 12
Calibration
- **Sligo General Hospital – Histology/Cytology**
Medical Testing
- **Environmental Protection Agency, Kilkenny**
Testing Laboratory
- **Enfer Labs Co, Co. Kildare**
Testing Laboratory
- **Louth/Meath Hospital Group, Our Lady of Lourdes Hospital**
Medical Testing
- **Medlab Pathology Ltd, Dublin 18**
Medical Testing
- **Mercy University Hospital, Cork**
Medical Testing
- **Cumhlucht Iascaireachta Fanad Teoranta**
t/a Marine Harvest Ireland, Co. Donegal
Biological Testing

EDITOR

Orla Ivers
Adrienne Duff

Project Executive
Manager, INAB

Email orla.ivers@inab.ie

The INAB Standard is published twice yearly and is available on www.inab.ie.

STATUS OF STANDARDS

Standard	Current Status	Next Publication/ Revision
ISO 17020	being revised at present, currently at formal approval stage	expected publication in 2012
ISO 17021	confirmed on 31-01-2011	due for revision in 2016
ISO 17025	confirmed on 15-12-2010	due for revision in 2015/16
ISO 15189	being revised at present public enquiry vote closed on 8-06-2011	close to publication
ISO 17065	being revised at present	target date to publish 31-07-2012
ISO 17024	being revised at present, the public enquiry vote closed on 16-09-2011	expected to be published in 2012

INAB will update its applicant and accredited clients as appropriate with transitional information, when new standards are issued.

INAB POINTS OF CONTACT

Manager

Adrienne Duff adrienne.duff@inab.ie

Administration

Katerina McKiver katerina.mckiver@inab.ie

Project Executive

Orla Ivers orla.ivers@inab.ie

Laboratory Accreditation

Marie O'Mahony marie.omahony@inab.ie
 Pat O'Brien patrick.obrien@inab.ie
 James Stapleton james.stapleton@inab.ie
 Sinead Guckian sinead.guckian@inab.ie
 Emma Scott McGrane emmascott.mcgrane@inab.ie
 Frank Crowe frank.crowe@inab.ie
 Annemarie Crowley annemarie.crowley@inab.ie

Certification Body Accreditation

Andrew Stratford andrew.stratford@inab.ie
 Brid Burke brid.burke@inab.ie
 James Stapleton james.stapleton@inab.ie
 Sinead Guckian sinead.guckian@inab.ie

Inspection Body Accreditation

Andrew Stratford andrew.stratford@inab.ie
 Brid Burke brid.burke@inab.ie
 James Stapleton james.stapleton@inab.ie
 Pat O'Brien patrick.obrien@inab.ie

Good Laboratory Practice

Marie O'Mahony marie.omahony@inab.ie

Forfás 
 INAB IS A DIVISION OF FORFÁS

Wilton Park House, Wilton Place, Dublin 2, Ireland.
 Tel: +353 1 607 3003 Fax: +353 1 607 3109
 Email: inab@inab.ie Web: www.inab.ie

