



INAB – A YEAR IN REVIEW



Tom O'Neill
INAB Chairman

Last year was once again a very busy year for INAB and its clients. During the past few years INAB has experienced continued growth in demand for its services and the major projects for INAB in 2010 included maintaining the accreditations already awarded through annual on-site inspections (289), managing new applicants, and supporting implementation of Regulation 765/2008.

In January 2010, INAB was appointed as the sole national accreditation body for Ireland. Regulation 765/2008 mandates that Irish conformity assessment bodies wishing to attain accreditation must do so from INAB. In essence, the possibility to choose another accreditation body outside of Ireland has been removed in keeping with the principle of no competition between National Accreditation Bodies. INAB has been working closely with other EA MLA signatory accreditation bodies to facilitate transfer of accreditation to INAB, as applicable.

The European cooperation for Accreditation (EA) which monitors the performance of national accreditation bodies in Europe together with the European Commission undertook a full evaluation of INAB during 2010 and confirmed that INAB would remain signatory to the international Multilateral agreements for accreditation of laboratories, inspection bodies, certification bodies certifying quality management systems, environmental management systems, and products. The staff and Board of INAB are justifiable proud of this outcome which confirms that INAB accreditation services are operated in accordance with best international practice.

Under the EA Multilateral Agreement, INAB, and the other signatories, assess and award accreditation according to the criteria specified in the relevant European Standards, published in the ISO/IEC 17000 and EN 45000 series of standards. The EA MLA agreement promotes uniformity between all signatories, and signatories to this agreement recognise and

accept each other's function and schemes as equivalent and the reports/certificates issued as equally reliable.

During 2010, INAB continued to experience very significant growth in demand for medical laboratory accreditation to the international standard ISO/IEC 15189. This demand initially arose from the requirements of the Department of Health and Children and the Irish Medicines Board for accreditation to ISO/IEC 15189, arising from national legislation with Statutory Instrument S.I. No. 360 of 2005. This S.I. required hospital blood banks to operate to ISO 15189 and by the end of 2010 INAB had awarded accreditation to forty-nine hospital laboratories for their blood transfusion activities. Arising from development in hospital services generally, applications for accreditation to ISO/IEC 15189 from these laboratories for their other medical testing disciplines such as microbiology, chemistry, etc. continued to grow during 2010 and makes it the area of greatest growth in demand for accreditation into 2011, in addition to being an area of significant strategic importance to the future direction of medical service delivery within Ireland.

In 2010, INAB established a Medical Advisory Committee (MAC) to provide advice and policy direction to the INAB Executive and Board on matters relating to medical laboratory accreditation. The MAC met three times in 2010 with a similar schedule and a comprehensive work-plan in place for 2011.

In 2010, INAB maintained and extended accreditation for certification bodies providing food quality assurance schemes for food products to international requirements, as well as national food quality assurance schemes, such as the Bord Bia and Bord Iascaigh Mhara schemes. Food product certification will continue to be a growth area for INAB for the foreseeable future.

INAB managed accreditation programmes for 7 inspection bodies that provide cylinder pressure testing, surveying for Asbestos, farm inspections, and in-service engineering inspection.

STATEMENT OF ACTIVITY 2010

Maintain Existing Accreditations	176
New Applications	27
New Accreditations Awarded	29
On-site Visits	289
Staff	12

INAB successfully initiated an accreditation programme in co-operation with the Department of Agriculture, Fisheries and Food for the accreditation of Certification Bodies to EN 45011 as required

under Council Directive 2092/91. The Directive requires that Certification Bodies certifying produce as organic must be accredited and by the end of 2010, INAB accredited the two Irish bodies operating this scheme.

The Irish National Accreditation Board is the designated competent body for EMAS and currently has 7 registered EMAS sites.

In 2010 INAB maintained four GLP approved test facilities in this programme. During 2011, INAB will undergo an evaluation of its GLP programme by the Organisation for Economic Co-operation and Development (OECD).

Increasingly Irish regulators are relying on INAB accreditation to support implementation of European and national legislation. This is precisely the model and desired direction envisaged by the European Commission in minimising regulatory burden, avoiding duplication and availing of a harmonised reliable mechanism to implement regulation.

INAB will continue to co-operate with Government Departments and State Agencies in the development of strategic accreditation programmes for new activities that are required to support regulatory functions.

Further developments that were initiated in 2010 and will follow through into 2011 include:

- The implementation of Phase III of the GHG emissions scheme in co-operation with the Environmental Protection Agency (EPA).
- The implementation of the EMAS III programme in co-operation with the Department of Environment, Heritage and Local Government (DOEH&LG).
- The implementation of a pilot programme initiated by the European Commission on the accreditation of environmental technology verifiers.
- The initiation and implementation of an EPA requirement that contractors sampling and testing air emissions be accredited to ISO/IEC 17025 by 2014.
- INAB will continue develop its accreditation processes for the purposes of notification and product safety directives.

INAB reviewed our fees in October 2010 and a 2% reduction was introduced to the schedule of fees for 2011.

The INAB Board has 12 members appointed by the INAB Board and Forfás. In 2010, the Board reappointed Vagn Andersen (Danak) and Nuala Bannon (Dept of the Environment, Heritage and Local Government) to the INAB Board. The Board met 6 times and awarded 29 accreditations in 2010.

I would like to thank all our clients for their support and cooperation during the year and we look forward to working with you in 2011 and building on the achievements of 2010. Finally I would like to express my sincere thanks to our Board members and the INAB executive for their professionalism and commitment over the year.

INAB PEER EVALUATION SUCCESS

Adrienne Duff – INAB Manager

In July 2010, INAB was subject to an EA (European Co-operation for Accreditation) peer evaluation by a five person EA team for one week. The comprehensive evaluation assessed INAB's management system on site at INAB offices and implementation of its programmes through witnessing client assessments. The evaluation was to ISO/IEC 17011:2004 Conformity assessment – "General Requirements for accreditation bodies accrediting conformity assessment bodies" and the applicable requirements of Regulation (EC) 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing regulation (EEC) No. 339/93.



European co-operation for Accreditation

Under Regulation 765/2008, INAB was appointed as the sole national accreditation body for Ireland by Department of Jobs, Enterprise and Innovation. Under Article 10 of this Regulation, each Member State Accreditation Body must be subject to a peer evaluation by EA, the organisation charged with management and monitoring of the European accreditation system (Article 14).

I am very pleased to inform our clients and stakeholders that a small number of findings were identified and these have been addressed through effective corrective actions. The report on the evaluation and INAB's response to address findings were presented and discussed at the recent meeting of the decision making arm of EA, the multi-lateral agreement council, in Serbia in April 2011. At that meeting, it was decided that INAB remain signatory to the multi-lateral agreements for testing and calibration (ISO 17025 and ISO 15189), inspection (ISO 17020), management systems certification (ISO 17021) and product certification (ISO Guide 65/EN 45011). The next EA evaluation is scheduled for mid-2014.

INAB's continued signatory status and confirmation as a competent accreditation body provides our accredited clients with the benefits that result from membership of the European and International multi-lateral agreements.

I would like to take this opportunity to thank all INAB staff and the INAB Board for their hard work in securing this successful outcome.



STACK EMISSION TESTING AND ACCREDITATION TO ISO/IEC 17025

Over the last 12 to 18 months, INAB has held a number of development meetings with the EPA (Environmental Protection Agency) to review a number of options available to it in developing acceptable competence requirements for organisation providing stack emission testing. The EPA concluded that to ensure that the monitoring of process emissions is performed correctly it needed to be carried out by third party verifiable accreditation (ISO/IEC 17025).



For those organisations undertaking this monitoring (emission measurements), the EPA will require them to be accredited by 2014. The assessment for accreditation to ISO/IEC 17025 will be carried out in conjunction with CEN/TS 15675:2007 "Air quality – Measurement of stationary source emission".

On the 1st June 2011 the EPA and INAB held a joint workshop in Athlone where the accreditation requirements and processes were fully explained to a large number of interested stakeholders. The EPA outlined its policy, and objectives and the view of a number of interested parties were also presented.

In anticipation of receiving applicants for this sector INAB has put in place the resources needed and applicants are reminded to submit applications well in advance of any deadline.



TRANSITION STATEMENT FOR ISO 14065:2007

The European Co-operation for Accreditation (EA) has adopted ISO 14065 as the standard to be used by its member accreditation bodies to assess requirements for greenhouse gas (GHG) verification bodies.

The timeline specified by EA is that all GHG verifiers should be accredited to this standard by January 2013.

In order to meet this deadline, INAB will be conducting conformity assessments to this standard during surveillance visits in 2012.

All verifiers are required to submit application forms/extension to scope application forms (if already accredited) for assessment of compliance to this new standard by December 2011. When submitting the required application form, all verifiers are required to submit updated documentation reflecting the organisations' changes to ensure conformance to the requirements of ISO 14065.

As all accredited GHG verifiers are expected to be in full compliance with ISO 14065:2007 by 1st January 2013, any identified nonconformities related to the new standard must be fully cleared. If, for whatever reason, nonconformities have not been cleared by 1st January 2013, a new certificate against ISO 14065:2007 cannot be granted, and accreditation will effectively cease on that date.

INAB will be holding an information session on the ISO 14065 standard in October, exact date to be confirmed. This is a session the GHG verifiers will be welcome to attend and invitations will be issued in due course.

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EMAS EVALUATION

A peer evaluation of INAB (Irish National Accreditation Board) took place from 12th to 16th July 2010, as required by Article 4, Clause 8 of the EMAS Regulation (EC) No. 761/2001 of March 19, 2001 and the corresponding mandate of the FALB. It took place at the same time as the EA Peer Evaluation.

The evaluation was based on the requirements of the EMAS Regulation and confirmed INAB's operations are in accordance with requirements, with no non-conformities raised.

OECD RE-EVALUATION OF INAB GLP COMPLIANCE PROGRAMME – OCT 2011

INAB had its first EU/OECD evaluation visit in 1999, when a team of 5 international GLP experts conducted a week long evaluation of INAB's National GLP compliance monitoring programme. This visit and its successful outcome were presented to the OECD working group meeting in September 2000.

INAB's next evaluation visit is scheduled for October 2011. A re-evaluation programme was established to provide continued assurance that compliance monitoring authorities, like INAB, continue to operate effectively.

The emphasis of this on-site re-evaluation visit will be on the observation by the OECD GLP team of an INAB GLP inspection (and study audits) at a test facility.

The report from the re-evaluation will be presented to the OECD GLP expert group in Paris in 2012, and subject to a successful outcome, the report will provide continued confidence to the members in INAB's national GLP Compliance programme, thus minimizing the need for individual monitoring programme to perform inspections and/or study audits in Ireland.

The Irish National Accreditation Board 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.

Data quality and integrity are assured by compliance with the OECD Principles of Good Laboratory Practice (GLP) and by national GLP Compliance Monitoring Programmes which implement the guidance established by OECD.

Confidence in other countries GLP Compliance Monitoring Programmes is crucial to supporting pre-marketing (pre-manufacturing) evaluation and for assuring public health and environmental protection.

The OECD system of Mutual Acceptance of Data (MAD) is intended to promote the efficient and effective protection of public health and the environment.

The OECD Working Group on GLP has established a programme of periodic evaluations intended to assess the extent to which member countries implement the 1989 OECD Council Decision-Recommendation on Compliance with GLP.

The objective of the periodic on-site evaluation programme is to enhance confidence that data receiving authorities throughout the OECD member countries are provided with accurate and complete assessments of the conduct of non-clinical health and environmental safety studies and of the quality and integrity of data used to support pre-marketing (pre-manufacturing) applications.

The periodic on-site evaluation programme also provides a mechanism for national GLP compliance Monitoring Programmes to gain increased confidence in the compliance monitoring practices of other member countries. Such confidence will permit Monitoring Programmes to provide timely and accurate compliance information about foreign test facilities to their respective data receiving authorities for their use in evaluating the quality of data submitted for their review and assessment.

The on-site evaluation programme is overseen and managed by the Working Group (WG) on GLP, which reports periodically to the Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology.

Complete cycles of on-site evaluations of all GLP Monitoring Programmes in the framework of MAD are carried out every ten years, and the first round of on-site evaluation visits began in 2008.

The Working Group on GLP currently comprises 50 GLP Monitoring Programmes, including those of the full non-member adherents to the MAD Council Decisions.

THE CONCENTRATE MANUFACTURING COMPANY OF IRELAND

PepsiCo, Little Island Business Park, Cork

The Concentrate Manufacturing Company Ireland are presented with their accreditation certificate for Laboratory Testing – Registration Number 268T by Tom O'Neill, INAB Chairman.



(L-R) Catriona Sheehy, Analytical Services Director, PepsiCo.; Tom O'Neill, INAB Board; Aisling Yeates, Quality Systems Co-Ordinator, PepsiCo.; and Elaine McDonnell, Ireland Q&TS Laboratory Manager, PepsiCo.

TRANSITION FOR INAB ACCREDITED BODIES TO ISO 17021:2011

The new International Standard ISO/IEC 17021:2011 has been published. This new edition sets requirements for the auditing of management systems and for auditor competence in order to increase the value of management system certification to public and private sector organisations worldwide.

For existing INAB accredited certification bodies, transition plans and progress towards completion will be assessed during headquarters surveillance visits. INAB expects the transition plan to be finalised and submitted with PS10 documentation, for assessment in full to the new standard at the 2012 visit.

All accredited certification bodies are expected to be in full compliance with ISO 17021:2011 by 1st February 2013, with any identified nonconformities related to the new standard fully cleared. Accreditation to ISO 17021:2006 will cease on 1/2/13.

To ensure INAB meets this deadline comprehensive evidence to clear any non conformities raised must be supplied to INAB at the latest by 1st Dec 2012.

Any new application for accreditation by certification bodies will be assessed to be to ISO/IEC 17021:2011.

WORLD ACCREDITATION DAY – JUNE 2011

June 9th 2011 will mark World Accreditation Day, a global initiative jointly established by the International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC) to raise awareness of the importance of accreditation-related activities.

INAB have communicated an information leaflet to relevant industry and government stakeholders on Accreditation, INAB and World Accreditation day.



GLOBAL LAUNCH OF IAF SURVEY – END USERS OF CERTIFICATION

The aim of the initiative is to collect and analyse feedback from **users of certification**, to ascertain the drivers for seeking it, and the value it provides.

The survey was launched in over 55 countries by the International Accreditation Forum (IAF).

In April 2011, INAB sent a web link of the survey to our accredited certification bodies encouraging onward distribution to their existing and potential clients (end users of certification). Link to survey below:

<http://www.surveygizmo.com/s/298130/iaf-certification-survey-ireland>

The survey closes in September 2011. Responses will be reported at the IAF General Assembly that will take place in November 2011, before being made publicly available.

Thank you in advance for your co-operation with this initiative.

CG POWER SYSTEMS IRELAND

Dublin Road, Cavan

CG Powers were accredited by the Irish National Accreditation Board (INAB) to undertake testing as detailed in their Schedule bearing the Registration Number 269T in compliance with the International Standard ISO/IEC 17025:2005 2nd Edition "General Requirements for the Competence of Testing and Calibration Laboratories".



(L-R) Mr Jack Blackett, INAB Assessor; Mr Patrick O'Brien INAB Accreditation Officer; Mr Jeby George and Mr James McMahon, CG Power Systems; and Mr Lawrence Cronin (INAB assessor).



ACCREDITATIONS AWARDED IN 2011 BY INAB BOARD

- **Cruinn Diagnostics Ltd t/a CruinnCal, Dublin 12**
Balance Et 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
- **Sligo General Hospital**
Medical Testing Laboratory
- **Airmid Health Group t/a Airmid Health Laboratory**
Testing Laboratory
- **Mattest (Ireland) Ltd, Dublin**
Testing Laboratory
- **Maha Ireland Ltd**
Calibration Laboratory
- **Lennox Laboratory Supplies**
Calibration Laboratory
- **Mattest (Ireland) Ltd, Cork**
Testing Laboratory

EXTENSIONS TO SCOPE AWARDED AT INAB BOARD

Medical Testing activities:

- Bon Secours Hospital, Dublin.
- Kerry General Hospital.
- Tullamore Midland Regional Hospital.
- St Lukes, Kilkenny.
- Naas Hospital, Kildare.
- National Maternity Hospital, Dublin.

Calibration activities:

- Butler Transtest Ltd, Kildare.

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NEXT EDITION – LAST QUARTER 2011

INAB will be preparing a special sectoral edition on the Medical Sector and Accreditation.

The INAB Standard is published twice yearly and is available on the INAB website.

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