

The Irish National Accreditation Board (INAB)

Summary of role and activities

Presentation to IEQAS

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Presentation overview

- Background and Role of INAB
- Accreditation Process
- International Recognition of INAB
- Key Benefits of Accreditation

INAB

- Established in 1985, a division of Forfás, Irelands National Policy Advisory Body for Enterprise and Science
- In January 2010, the European Commission was notified by the Department of Enterprise, Trade and Employment (now the DETI) as being the sole accreditation body for Ireland in line with regulation EC/765/2008.

INAB

- 9 Accreditation Officers
- Support services provided by Forfás (Financial/IT/HR)
- INAB has independent Board appointed by the Forfás Board and include representatives from state agencies, industry and consumer interests.
- Expert committees (E.g. Medical Advisory Committee)
- >80 contracted technical experts/assessors
- Approx. 160 Accredited Organisations (Labs/Certification bodies/Inspection bodies)

INAB

- The Irish National Accreditation Board provides accreditation to international standards to:
 - Laboratories (ISO 17025, ISO 15189)
 - Certification Bodies (ISO 17021, ISO 17024, ISO Guide 65)
 - Inspection Bodies (ISO 17020)

INAB: Statutory Functions

- Statutory monitoring body for OECD/EU GLP (Good Laboratory Practice) Regulations - S.I No.4 of 1991 and S.I No. 294 OF 1999
- Competent Authority for the Registration of EMAS sites
- Other statutory functions.

INAB: Statutory Functions

Regulation 765/2008 provides legal framework for the provision accreditation services across Europe.

- Since Jan 1st 2010, CAB's are required to seek accreditation from their National Accreditation Body (NAB), except;
 - If there is no NAB within the Member State
 - The NAB is not signatory to the MLA for the activity
 - Where the NAB does not offer accreditation for the activity sought

What is Accreditation?

Third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks (scope)

- *Taken from ISO 17011- Conformity assessment, general requirements for accreditation bodies accrediting conformity assessment bodies*

The Accreditation Process (New Applicant)

- Application to particular standard & scope
- Pre-assessment
- Assessment
- Decision on award of accreditation (INAB Board)

The Accreditation Process (Member)

- Surveillance / ongoing monitoring / extend scope
- Reassessment after 5 years (new team)
- Surprise / unannounced visits
- Additional visits

Accreditation Process: Time-frame

- Application
- Pre-assessment (2 months)
- Assessment (3 - 6 months)
- Corrective actions (3 months)
- Decision on Accreditation (3 months)
- Re-assessment (4.5 years)

Accreditation Process

- Application - General application form completed by laboratory
Quality Manual / Requested scope
- Assign assessment team (By Discipline)
Documentation review by team
- Pre-assessment (1 day)
On-site visit
Identify gaps
Discuss scope
Meet technical & quality management / staff

Accreditation Process

Assessment

- Opening Meeting
- Discuss / Agree Scope
- The day is comprised of interviews, test witnessing, records review, review Internal/external Quality assurance (Quality systems & technical competence)
- Observations - AF117 - Factual Statements

Accreditation Process

- Proposed corrective actions
- MF116 assessment trail report
- Private assessor meeting
- F118 summary report

Accreditation Process

- Submission of responses
- Review by assessment team
- All non-compliances satisfactorily addressed
- Report to Board of INAB for decision
- Accreditation awarded for 5 years
- Annual surveillance visits - extension to scope

Medical Laboratory Accreditation

- The standard (ISO 15189) emphasises patient needs.
- Addresses issues particular to a medical laboratory which include the provision of advisory services, collection of patient samples, provision of testing in a medical emergency and the contribution of the medical laboratory service to patient care.
- INAB uses a combination of technical experts and medically qualified assessors from EA Accreditation bodies who have significant experience in medical laboratory accreditation.

INAB Medical Advisory Committee

- Committee established by INAB for the sole purpose of offering advice to the INAB Executive on issues of principal importance in the accreditation medical field.
- First meeting March 2010
- 11 Members representing end users of the accreditation scheme.
- Task Force Groups

EA Laboratory Medicine Working Group

- Permanent Working Group of the Laboratory Committee / Meets Twice per year
- Permanent representative from INAB
- Current Chair - from SAS, Swiss Accreditation Body
- Discuss and Review:
 - *Harmonised approach to implementation of ISO 15189*
 - *Need for guidance within certain sectors*
 - *Technical issues*

International Recognition of INAB

INAB is signatory to EA Multi-lateral agreements (MLA)

- ✓ MLA requires INAB to operate in accordance with international standards and protocols (ISO 17011)
- ✓ Multilateral Agreements (MLAs) with EA, ILAC and IAF ensure international recognition of INAB accreditation
- ✓ Regular international evaluations of INAB to reconfirm INAB's continued membership of these MLAs

ISO 17011

“General requirements for bodies providing assessment and accreditation of conformity assessment bodies (CAB’s)”

- Similar structure to accreditation standards - quality system & technical components
- Legal status, impartiality, confidentiality, competence
- Complaints, non-conformances, audits
- On site assessment, records, PT, assessor competence, visit intervals
- Granting, removing, renewing accreditation

Who accredits the Accrediting Bodies?

- The IAF and ILAC call for each accreditation body to be recognised by its peers as being in compliance with ISO 17011.
- Although there is no Accreditation Body for ISO 17011, IAF & ILAC have formal Memoranda of Understanding with each other and all authoritative International organisations.

International Recognition of INAB

The European co-operation for Accreditation (EA) is the European Association of National Accreditation Bodies.

- ✓ Carry out regular on-site evaluations to verify INAB's continuing compliance with the International accreditation standards to re-affirm INAB's signatory status to the MLA.
- ✓ Develop and promote accreditation criteria and guidelines which ensure harmonised performance of national accreditation bodies throughout the European Economic area.

European Co-operation for Accreditation (EA)

- EA - non profit making organisation set up November 1997 (currently 33 members)
- EA - European Network of nationally recognised accreditation bodies
- EA - an active member of ILAC (International Laboratory Accreditation Forum) and IAF (International Accreditation Forum)

Purpose of EA

- Gives Europe and effective accreditation infrastructure
- Develops accreditation criteria and supports harmonisation
- Operate a sound, robust, reliable peer evaluation process
- Ensure equivalence of accreditation and equal reliability of accredited results
- Co-operate with the European commission and other European, international stakeholders.

The International Dimension

In the broader international arena, the World Trade Organisation's (WTO) agreement on Technical Barriers to trade recognises the importance of accreditation and two other organisations undertake the functions described for the EA

- ❖ IAF (International Accreditation Forum)
- ❖ ILAC (International Laboratory Accreditation Cooperation)

The aim is to achieve global accreditation structures and worldwide mutual acceptance of accreditation

The International Dimension

- ✓ The EA MLA is recognised at International level by ILAC and IAF
- ✓ A test report or certificate accredited by an EA MLA signatory can be recognised also by the signatories of the ILAC and IAF multilateral agreements, the EA MLA acting then as an international passport to trade.

What are the Benefits of INAB Accreditation?

- Provides assurance on the integrity and accuracy of the laboratory results and outputs and is a formal recognition of its technical competence.
- Increases confidence in accuracy of laboratory results on which decisions can be made and ensures decisions are made on comparable data.
- Increases public confidence.

What are the Benefits of INAB Accreditation?

- Awarded by an Independent body that is objective, impartial and transparent.
- International Acceptance of Data through European and international Multilateral Agreements .

Thank you