The INAB Standard
www.inab.ie
THE NEWSLETTER OF THE IRISH NATIONAL ACCREDITATION BOARD Summer 2020 | EDITION 39

World Accreditation Day - Improving Food Safety

June 9th 2020 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. The theme of the day this year is 'Improving Food Safety'.

In complex and highly competitive markets, a level of confidence is required when procuring products or services. Such reassurance is underpinned by accreditation.

Accreditation provides an independent and authoritative attestation of the competence, impartiality and integrity of conformity assessment bodies (CABs) – laboratories, inspection bodies and certification bodies.

Standards and accreditation play an increasingly important role in contributing to and improving food safety across the whole of the food supply chain from farm to fork helping build layers of assurance in the supply chain; at food production, processing and packaging, storage and transportation, to retail and catering.

INAB will promote World Accreditation Day on our website, social media platforms and are preparing a food publication on the benefits of accreditation in the food sector.

Link to WAD video; and Brochure

#WAD2020

INAB - 35 years in Accreditation

INAB are delighted to announce that we are 35 years old in 2020!
Our Winter Newsletter will be dedicated to celebrating this, looking back, where we are now, and what the future holds for accreditation and INAB.

INAB COVID-19 Information

We are all aware of the restrictions that the Coronavirus is placing on our businesses and personal lives. In these extraordinary times, INAB continue to operate as normal, while following Government advice and guidelines:

- INAB staff is now entirely remote and working from home
- INAB is undertaking remote assessments, where it is suitable and appropriate to do so– this is expected to continue for some time.
- New documents, like the NF23, have been issued to support remote assessments and a FAQ prepared and links to relevant websites available

All covid-19 related INAB information is available from the yellow banner on our homepage **www.inab.ie** – we will continue to update and advise of any changes as they occur.

IAF and ILAC have recently released this video **Accreditation in the Fight Against COVID-19**, available on the IAF/ILAC Youtube channel.

EXPERIENCE OF A INAB REMOTE ASSESSMENT – ROTUNDA HOSPITAL– April 2020

Susan Luke, Laboratory Quality Manager and John O Loughlin, Laboratory Manager, Rotunda Hospital

The Department of Laboratory Medicine in the Rotunda Hospital has been accredited by INAB to ISO15189 for many years in all five major disciplines. In recent years, we added point-of-care accreditation to standard ISO22870.

Our annual onsite assessment was due on April 21 2020. This coincided with the SARs Cov2 outbreak and resulting pandemic. Following the publication of INABs document on remote assessment (NF23 and IAF ID 12:2015 - Principles on remote assessments), we opted for a remote assessment, a decision not taken lightly, considering we were down several staff who were either Covid19 positive or in self isolation. Anxiety levels in the laboratory were high.

How we planned for the visit?

- We worked very closely with our INAB officer William
- Identified key PCs and mobile devices and uploaded webex and zoom.
- Sourced headsets and speakers from ICT Department
- Had practice run of the opening meeting with our INAB officer, assessors and staff.

Documentation requested by each assessor was uploaded to CRM in the days leading up to the assessment. One difficulty we had was the size of files due to volume of documentation in some areas.

The day of the remote assessment

The remote assessment began as any other; we had a successful opening meeting on Webex. The meeting was attended by assessors and staff located in the Rotunda, remotely from home and indeed from across Europe.

A plan was agreed as to how the day would proceed and appointments made to speak by telephone to key individuals such as the consultant leads. As the day progressed, many calls took place and further documentation requested and either viewed on screen share in Webex or more often uploaded onto CRM. A key point is to have a designated staff member who can efficiently collate and upload the considerable amount of documentation requested throughout the day.

Deidre O Neil – Senior Medical Scientists in Blood Transfusion using Webex during the assessment.

The laboratories were able to facilitate assessors viewing processes by using mobile phone cameras and microscopes with images linked to a PC enabling us to live stream back to assessors. Our building built in 1759, the IT facilities, and infrastructure did not hinder either side in auditing processes.

The day ended with a review of some non-conformances raised, this was probably one area which could be improved as unlike conventional visits in some areas they were not aware of the NC batches until the closing meeting or as the nonconformance's were uploaded onto CRM.

The closing meeting followed the format of an onsite visit.

How did the Laboratory staff feel post assessment?

Overall, the laboratory staff felt the assessment was robust and detailed. Some staff were very hesitant about partaking in a remote assessment, as there was so much uncertainty. However, post assessment, all of the staff agreed our systems had been audited with the usual investigative manner as if assessors were on site. We were glad we had gone ahead with the remote visit for 2020.

What where your key learnings from your remote assessment?

- In preparation, liaise much closer with your INAB officer than you would normally do. This is learning for both.
- Identify and prepare designated PCs for use on the day.
- Upload software such as Webex or Zoom. This may require ICT input so this should be done well in advance of the visit.
- Have a designated person available and free to upload requested documents onto CRM and navigate Q-pulse.
- Test all systems with your INAB officer in advance of the assessment.
- Use all tools at your disposal such as microscope cameras, live streaming using mobile phones or equivalent.
- Work with the assessors as this is new for them also.
- Expect and forgive any minor technical glitches that happen during the assessment. Work around them.
- Prepare your staff and address any issues or concerns well in advance of the visit.
- Plan your day in advance i.e. staffing levels, maintaining social distancing, remote workers, remote access, ICT support, PPE and so on.

INAB would like to thank the Rotunda for their feedback on their remote assessment.

EA Certification Committee

The 39th meeting of the EA Certification Committee scheduled for Sofia in March was cancelled. Meeting documents were circulated and it is planned to make progress on issues remotely. The EA Policy for the Accreditation of Organic Production Certification (EA-3/12) is under revision and is currently out for voting. The work plan for 2021 was agreed. The remit of the Certification Committee also includes ISO/IEC 17029. It is also intended to discuss the implementation of remote techniques concerning IAF ID12 and IAF MD4, which are obviously pertinent in the current circumstances.

Plans for the September meeting have not been finalised yet but it is likely to proceed remotely.

IAF - Covid Updates Related to Certification

FAQ Section

The IAF website has a **FAQ section** dealing specifically with questions related to the COVID-19 situation and its implications for accreditation and certification. This is a useful resource for certification bodies and provides a common understanding and guidance in managing conformity assessment activities at this time.

Transition Period extensions

- Application of IAF MD5:2019 and IAF MD 22:2019 extended by 6 months to 7 November 2020.
- The end of the transition period for ISO 22000: 2019 is now 19 December 2021 and for ISO 50001:2018 it is now 21 February 2022.

Certification bodies should consult the following documents at this time:

IAF ID 3:2011 Informative Document for Management of Extraordinary Events or Circumstances Affecting ABs, CABs and Certified Organizations

IAF MD 4:2018 IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes

Please note that the following extracts from IAF ID 3:

- *The CAB should assess the risks of continuing certification and establish a documented policy and process, outlining the steps it will take in the event a certified organization is affected by an extraordinary event.*
- *All deviations from the established certification program should be justified, documented and made available to ABs upon request.*

INAB To Introduce Accreditation to ISO/IEC 17029:2019

ISO/IEC 17029:2019 is a generic standard and viewed as coming somewhere between inspection and certification. The object of conformity assessment will be information declared by the client, and the validation and verification will involve the confirmation of the claim through the provision of objective evidence.

INAB is currently reviewing resource and process requirements with a view to offering and accepting applicants under this new accreditation standard in the second half of 2020.

ISO/IEC 17029:2019, Conformity assessment — General principles and requirements for validation and verification bodies, has been issued and a training course for accreditation bodies was held in Paris in November 2019. An INAB representative attended the course.

Validation is the confirmation of a claim through the provision of objective evidence that the requirements for a specific intended future use or application have been fulfilled (confirmation of plausibility).

Verification is the confirmation of a claim through the provision of objective evidence, that specified requirements have been fulfilled (confirmation of truthfulness).

It is intended that this standard can be applied in any sector, in conjunction with sector specific programmes that contain requirements for validation/verification processes and procedures. Validation/verification bodies can provide validation/verification as a first party, second party or as a third party activity. Bodies can be validation bodies only, verification bodies only, or provide both activities.

SARS-COV-2 (COVID-19) TESTING

INAB has recently issued a notice to laboratories interested in applying for accreditation for Covid 19 testing. Please see the following **link to our website**. Please contact your INAB assessment manager for more details.

TRANSITION TO ISO17025:2017

Transition assessments of testing and calibration laboratories to ISO17025:2017 is in progress and all visits to these laboratories are being completed according to the new revision. Approximately 80% of laboratories have successfully transitioned with many more in the process of assessment and decision. All laboratories will need to have successfully completed this transition process by November 2020.

New Or Changed Technical Policies

Point of care testing (POCT) ISO22870.

PS31 was recently issued by INAB. It concerns additional requirements for assessment of ISO15189 / ISO22870 applicant or accredited laboratories. The policy ensures that INAB completes a more structured assessment of Point of Care testing activities. Please note this policy is active only from January 2021 and will be applicable for all assessments, from then.

Scope formats

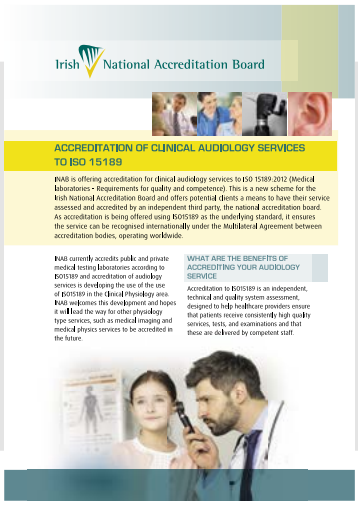
PS 34 is a new policy being prepared on the formatting of scopes of ISO17025 testing laboratories. The main aim of this document is to harmonise the layout and information available on the publicly available scope document. It will help the end user in reviewing and choosing their test laboratory and provides a greater transparency to other users, INAB assessment teams, regulatory authorities and other stakeholders. It is planned that this policy will include scope formats for ISO15189 laboratories, later in 2020. An announcement will be made once this document is approved and published to all relevant parties.

NEW FOR 2020

INAB LAUNCH NEW CLINICAL AUDIOLOGY SCHEME

In March 2020, INAB announced our new scheme offering accreditation for clinical audiology services to ISO 15189.

This scheme is open to all hospital audiology services and HSE community-based referral centres. Contact Scheme Manager, Brid.burke@inab.ie for further information. Click image to access the electronic leaflet.



Accreditation of Bio banking according to ISO20387

NAB plans to have this accreditation scheme structure in place by the end of 2020. We are currently consulting with other EA accreditation bodies in developing this scheme. Competence requirements for INAB assessors and scope formats for the accreditation bodies are currently being discussed. At this stage, INAB would be interested in hearing from any parties who wish to apply for this accreditation. For expressions of interest in this scheme, please contact brid.burke@inab.ie

Unfortunately, all EA meetings have been cancelled due to the Covid 19 pandemic. This is likely to be the case for the remainder of 2020, due to travel restrictions. However, the groups continue to exchange information electronically. We expect these meetings will resume in 2021.

INAB Extend Multilateral Agreement with ILAC to Include Reference Materials Producers (RMP)

In April 2020, INAB extended the scope of its multilateral arrangement with ILAC to include accreditation of reference material producers. The scope of the ILAC MRA includes:

Testing ISO/IEC 17025 and ISO 15189	2 November 2000
Calibration ISO/IEC 17025	2 November 2000
Inspection ISO/IEC 17020	24 October 2012
Reference Material Producers ISO 17034	17 April 2020

INAB has signed the ILAC R7-F1 licensing agreement to use the Combined ILAC MRA Mark, the use of this Mark is now extended to include our RMP accreditation scheme. We encourage our accredited CABs to use the Accredited CAB Combined ILAC MRA Mark.

Click here for full information on how accredited CABs can apply to use the combined ILAC MRA mark.

Certification bodies can use the IAF MLA mark – click here for further details.

EA MLA REPORT 2019

The EA Multilateral Agreement (MLA) report 2019 issued in April 2020. The EA Multilateral Agreement (EA MLA) report provides information on the signatories to the EA MLA, as well as an overview of the key activities completed in 2019 to further develop the coverage of the EA MLA and to strengthen the operation of the EA peer evaluation system, including management of EA evaluators.

INAB Implements Actions From Client Satisfaction Survey

In mid-2019, INAB conducted a client survey, which focussed on personnel handling and service to our clients. The focus of our recommendations was to improve our service to our clients. This month we are launching our Customer Charter. We have also recently introduced the central management of our client's queries through the CAB portal system. Both documents are available in the table below.

Other recommendations are underway, including a review of the Scheduling Process, looking at the internal processes and systems.

NEW - INAB CUSTOMER CHARTER

INAB is committed to providing a professional, efficient and courteous service to all our clients. Click on the image here to see our new Customer Charter.

HOW TO CONTACT YOUR ACCREDITATION OFFICER ON ACCREDIATION QUERIES?

INAB has introduced a new way to process queries from our clients.

The NF 26 -Notification on Accreditation Queries Functionality in CRM circulated at the start of April 2020.

Analysis of Extent and Cause – Clarification of INAB's Approach

A regular outcome from INAB assessments is the generation of nonconformities. In order to clear them, conformity assessment bodies (CABs) must respond back to INAB, detailing actions taken.

Clause 7.6.8 of the 2017 version of ISO 17011 prompted a change to INAB procedure in this regard:

> **7.6.8** When nonconformities are identified, the accreditation body shall define time limits for correction and/or corrective actions to be implemented. The accreditation body shall require the conformity assessment body to provide an analysis of the **extent** and cause (e.g. root cause analysis) of the nonconformities and to describe within a defined time the specific actions taken or planned to be taken to resolve the nonconformities.

The relevant part is highlighted in red, and the part that INAB is particularly interested in is in bold.

Basically, INAB assessors should not clear NCs unless the accredited body provides an analysis of extent and cause for every NC.

Recent experience has shown that analysis of extent is not clear in many responses from CABs; many are struggling with it as they were not obliged to provide it in the past. So, some examples are given here:

- An assessor identifies in an NC that competence records are not up to date for a lab technician for a particular test method. The laboratory should, in its response, confirm that it has checked that the out of date records did not extend to all of the other technicians (or if it did, that the records for all were brought up to date).
- An assessor identifies in an NC that a confidentiality agreement between a certification body and one of its auditors is deficient in some way. The CB should check all confidentiality agreements to determine if it was a one-off incident, or if it extended to other auditors, and include this information in its response.

In each case, if the issue extended to other personnel/areas, the response should confirm that the correction was applied to all affected personnel, not just for the individual example identified in the NC.

Directory of EU Legislation Related to Accreditation and Conformity Assessment

There are around 115 pieces of EU legislation, which refer to accreditation and conformity assessment. That demonstrates the role and value of accreditation in Europe.

In order to support the EA NAB members, CABs and other interested parties, a comprehensive directory of EU legislation with relation to accreditation and conformity assessment has been established.

This directory (EA-INF/05) is now available and published on the EA website https://european-accreditation.org/publications/ea-inf-05/.

INAB New Appeal Board Members

In January 2020, 3 external members were appointed to the INAB Appeal Board.

Applications were invited through the State Board appointments service in October 2019 from suitably qualified and experienced candidates for appointment to the INAB Appeal Board.

The appointed members were:

- independent of INAB and the bodies that it accredits;
- have not worked in a body that INAB accredits or assessed a body that INAB accredits within the previous 10 years;
- demonstrates knowledge in or expertise of, at an appropriately senior level one or more of the following:
  - accreditation
  - conformity assessment
  - the interests of national authorities and consumers of accredited services
  - investigation and consideration of appeals to decisions

The member of the Appeal Board were appointed for a 5 year terms from January 2020.

For further details, see our R1 Regulations - SECTION 8: Appeals against decisions of INAB.

Expressions of Interest: INAB Technical Experts/ Technical Assessors

The Irish National Accreditation Board welcomes expressions of interest from experts seeking to provide contracted professional technical services to INAB in support of its accreditation programmes. Expertise demand will vary from time to time.

INAB has an immediate need for and welcomes contact from potential assessors or technical experts in the following sectors:

Calibration laboratory accreditation

- Temperature measuring equipment
- Temperature controlled enclosures
- Ancillary temperature measuring equipment

Test laboratory accreditation

- Construction materials testing
- Chemical testing (drugs/drug residue analysis, food (including GMOs), gas emissions)
- Biological/veterinary testing (food and water microbiology)

Medical test laboratory accreditation

- Medically qualified experts in:
- Microbiology/virology/serology
- Blood transfusion science
- Haematology
- Audiology

Certification

- Sustainable farming
- Aquaculture (finfish and molluscs)
- GDPR

The full range and scope of INAB activities is documented on the website www.inab.ie

Candidates should have a third level qualification and more than 5 years' experience working in the applicable sector. Formal assessor training and previous experience working with an accreditation body would be a distinct advantage, but there may be vacancies for technical experts who may not have training in the relevant accreditation standard. If interested, please complete the IP25EX form (available for download on www.inab.ie) and return to the email address provided on the form.

A formal qualification procedure is in place and all applicants will be evaluated against documented criteria and current demand.

INAB ACCREDITATIONS AWARDED IN 2020

Currently INAB have 4 new accreditations awarded in 2020. Click **here** for further information.

To see the full directory of accredited bodies click **here**.

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The INAB newsletter will now only be available electronically please provide your email address to **inab@inab.ie** to subscribe. If you would like to unsubscribe, at any time, please email **inab@inab.ie**.

Resignation

Our colleague David Brown recently resigned from his role in the administration unit as clerical officer. We would like to express our thanks for his work and wish him well on his future endeavors.

Irish National Accreditation Board

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HEALTH AND SAFETY AUTHORITY

INAB is part of the HSA