



## National Association of Testing Authorities, Australia

### SISO Progress Report Supporting Information

#### Reporting Period

1 July 2022 to 31 December 2022

#### NATA ELIGIBLE ACTIVITY

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## **1. Maintain membership and participate in the International Laboratory Accreditation Cooperation (ILAC)**

### **1.3 Maintain High Level Participation in Relevant ILAC Committees**

The ILAC-IAF meetings scheduled during the July-December 2022 period were conducted virtually as a consequence of the ongoing COVID-19 pandemic. These are summarised on the spreadsheet 'NATA - activities'.

#### **ILAC/IAF Joint General Assembly (JGA)**

A summary was provided on progress towards the new single international organisation for accreditation:

- the Articles of Association have been drafted; and feedback received from the Steering Committee (SC), Joint Executive Committee (JEC) and ILAC/IAF members on the October 2022 version has been considered.
- the economy for registration is still to be finalised, possibly New Zealand
- tender will be called for common secretariat, to be operational by 1 January 2024
- agreement is yet to be reached in relation to stakeholder involvement and voting rights.

ILAC held an extraordinary GA in September 2022 following a request from several European Accreditation Bodies (AB) to discuss the proposed membership categories for the new organisation. Of particular concern is the proposal to include a category of membership for 'stakeholders' and the proposal that stakeholder members would have voting rights in the General Assembly and on the Executive Committee, albeit restricted to preserve a majority of votes for AB members. Both ILAC and IAF currently have a membership category for stakeholders and IAF allows stakeholder members a vote along the lines as being proposed for the new organisation. Jennifer Evans, as APAC Chair, presented APAC's position, which aligns with the current IAF position.

It was agreed at the November 2022 JEC meeting to get ILAC and IAF members to vote on stakeholder involvement and voting rights, as well as whether NZ is to be the economy for registering the organisation.

The next steps will be determined pending the outcome of these votes.

#### **General Assembly (GA)**

At the beginning of 2023, a tender will be issued for the secretariat of the new international organisation for accreditation as mentioned earlier. The Deed of Agreement between ILAC and NATA for secretariat support ends Dec 2023.

In May 2022 a Joint Statement of intent on the digital transformation in the international scientific and quality infrastructure was signed by - signing by ILAC, OIML, ISO and CIPM.

An MOU between ILAC, IAF and the International Telecommunication Union (ITU) was re-signed in August 2022.

ILAC's membership currently consists of 154 organisations, including:

- 108 signatories representing 116 economies
- 18 Associates representing 19 economies
- 22 stakeholders
- 6 regional cooperation bodies

There are currently over 85,000 laboratories, 13,000 inspection bodies, 600 proficiency testing providers and 250 reference material producers accredited by the ILAC signatories.

Several resolutions of relevance to NATA were passed at the GA:

### ILAC Resolution GA 26.08

- As the revised version of ISO 15189 is scheduled for publication in late 2022 or early 2023, the General Assembly endorses the recommendation of the Accreditation Committee (AIC) that a transition period of 3 years from the date of publication be adopted.

ISO 22870:2016 in conjunction with ISO15189:2012 will still be recognised as a Level 4 standard for POCT for the duration of the transition period since that the requirements for Point of Care Testing (POCT) contained in ISO 22870:2016 have been incorporated into the revised ISO 15189. At the end of the transition period, accreditation of a medical laboratory to ISO 15189:2012 and accreditation of POCT to ISO 22870:2016 in conjunction with ISO15189:2012 will not be recognised under the ILAC Arrangement.

### ILAC Resolution GA 26.09

- As the revised version of ISO/IEC 17043 is scheduled for publication in 2022 or early 2023, the General Assembly endorses the recommendation of the AIC that a transition period of 3 years from the date of publication be adopted.

At the end of the transition period, accreditation of a proficiency testing provider to ISO/IEC 17043:2010 will not be recognised under the ILAC Arrangement.

### ILAC Resolution GA 26.10

The General Assembly approved the procedures for the operation of the ILAC Stakeholder Forum (SF) as detailed in a document titled ILAC Stakeholder Forum Constitution 4 October 2022. The forum replaces the ILAC Laboratory Committee and is to be composed of *one* representative of each eligible ILAC stakeholder member. The core function of the SF is to enable committee members to act as a conduit between ILAC and the stakeholder organisations they represent. Key objectives of the SF revolve around those tasks which relate to accreditation activities undertaken by ILAC, add value to the accreditation system, support the concept “accredited once accepted everywhere” and ensure a harmonised and transparent accreditation system.

An update was provided from each of the Committee Chairs; refer to the separate meeting reports below.

### **Arrangement Council and Arrangement Committee (ARC)**

- Applications can now be submitted to ILAC from regional cooperation bodies for the evaluation of the recognition of their MRA/MLAs for the accreditation of biobanks as a result of the revision and publication of ILAC P4, P5 and R6 in June 2022. On the completion of the evaluation and recognition of a region for the accreditation of biobanks, the final step for the extension of the ILAC MRA to include this activity can be completed.
- Consideration is currently being given to the structure of the IAF MLA and ILAC MRA. Feedback has been received from the regions on the need for sub-scopes as part of the recognition of the regions to the IAF MLA and ILAC MRA. The feedback has been collated and is currently being considered by a Joint Management Committee (JMC) task force in preparation for discussion at the next JMC meeting.
- A JMC task force is being established to consider the issues surrounding the introduction of ISO/IEC 17029:2018 as a new IAF MLA scope and the potential overlaps with inspection body accreditation (and product certification for IAF). The aim is to help ensure there is common ILAC/IAF understanding and cooperation between those implementing these standards in relation to the activities that may fall under the scope of more than one of the standards.

### **Accreditation Committee (AIC)**

#### ISO/IEC 17025:2017 issues

ISO/IEC 17025 is due for its 5-year systematic review; and it has gone out to ballot closing in early March 2023. ABs were requested to inform the AIC chair if they believed that the standard needs revision including justification for the revision by mid November 2022. NATA will cast a vote to reconfirm the standard for another 5 years via Standards Australia Committee, QR-010.

The CASCO Secretariat launched a survey in September 2021 to collect feedback from users on the value of the 2017 version, its impact on their activities and processes, and the challenges or issues they might have encountered during the implementation. Over two-thirds of respondents noted improvements to the competence and management of their laboratories. Respondents also submitted improvement suggestions for the next revision of the standard. A workshop to discuss the standard is planned for May 2023 when a face-to-face meeting is anticipated. Topics for consideration include:

- MU arising from sampling
- management options A&B
- decision rules and conformity statements (and possible need for revision of ILAC G8)
- sampling in calibration

The regions have been invited to input issues they have dealt with since the standard was issued, and the AIC will continue to collect questions related to the implementation of the standard.

#### Liaison with IEC

IEC Guide 115 *Application of uncertainty of measurement to conformity assessment activities in the electrotechnical sector* is referenced in IEC CA Systems Operational Documents. It has been noted that ABs are either not using or recognising the Guide.

#### Equivalence of ISO/IEC 17025 and ISO 15189

The publication of the brochure “Specifying accreditation for Covid-19 testing” revealed that both ISO/IEC 17025 and ISO 15189 are used around the world for COVID-19 diagnostic testing. As the specifiers of accreditation typically are health authorities and they may not adhere to an AB’s preferred standard, AIC members were asked at the last AIC meeting to consider if there is a need for a statement of equivalence between the two standards (similar to the Joint ISO-ILAC-IAF Communique on the Management Systems Requirements of ISO 9001 and ISO/IEC 17025).

Many ILAC members objected to a statement of equality between the 2 standards. WG 15189 are to consider the objections and comments for future work at the face-to-face meeting(s) in 2023.

#### Liaison ISO TC 334 (former REMCO)

The outcome of the periodic ballot for the review of ISO 17034 confirmed the standard for another 5 years.

#### Webinar digital SI

A webinar on the digital SI project was held June 2022. Further information and access to presentations can be found through the link on the webpages:

<https://ilac.org/about-ilac/partnerships/international-partners/bipm/>

and <https://www.bipm.org/en/committees/ci/cipm/wg/cipm-tg-dsi/2022-06-30>

#### WG Scopes of Accreditation

The next face-to-face meeting of the AIC will discuss whether the year of the standard / method is to be included in scopes of accreditation.

#### UNIDO Project on flexible scopes

ILAC and IAF were asked by UNIDO to circulate a questionnaire to all MRA/MLA signatories as part of a project that UNIDO is currently undertaking in relation to flexible scopes. ILAC and IAF have no involvement in this project other than agreeing to distribute this information to members and to also review the final output prior to publication to ensure there is no conflict with ILAC and IAF.

A review of the UNIDO document, “*The application of flexible scopes of Accreditation. A benchmark study on the current use*” raised concerns about some of the content where information from the existing guidance documents (e.g. ILAC G18 and other regional documents)

had been repeated and mandatory language (such as “shall” and “must”) had been added. UNIDO accepted ILAC’s advice to include the results of the survey as information for any ABs wishing to adopt flexible scopes rather than to repeat information from current ILAC publications and/or regional documents and to remove mandatory language.

The UNIDO report will be included for discussion on flexible scopes of accreditation at the ILAC meetings in 2023.

#### WG Assessor Qualification

The Terms of Reference of the WG will to be updated to include remote training as it has become the new normal due to COVID-19. The WG is collecting information and experiences with remote training and will consider the need for development of an annex to ILAC G3 on this issue.

#### **Inspection Committee (IC)**

##### Updates from ISO/CASCO

ISO/IEC 17020 is due for systematic review; and it has been put out to ballot closing in early December 2022. It is expected that revision of the standard will be supported.

##### Planning for 2023 workshop – accreditation of inspection that utilises new technologies

A question was raised on whether there is a need for an ILAC document on the accreditation of new technologies used for inspection activities and if these new technologies should be identified in scopes of accreditation.

A workshop on this topic will be held in conjunction with the next face to face meeting in 2023. A request has been made for case studies/examples on the use of new technologies inspected (and how to assess these) to be provided by participants to assist in planning for the workshop.

##### Grain and Feed Trade Association (GAFTA)

ILAC is keen to further develop their relationship with GAFTA and have sought interested members to be included in a small group to discuss and progress cooperation/MoU with GAFTA.

##### OIML – the application of ISO/IEC 17020 to the assessment of OIML Issuing Authorities under the OIML-CS

An update on the progress of the OIML draft guidance document for the assessment of issuing authorities was provided. Development of an ISO/IEC 17020 assessment document is being developed by OIML on the use of ISO/IEC 17020 as an alternative standard to ISO/IEC 17065 and the revision of OIML B18. and volunteers were sought to review.

##### Verbal feedback was provided from regional bodies, including:

- IAAC - calibration of equipment used in inspections, competition between inspectors and discussion of new technologies (e.g. drones)
- EA - main topics being considered are impartiality and subcontracting
- AFRAC - planning workshops for metrological traceability and harmonisation of scopes, and consideration of NDT requirements

##### Topics for discussion at the next meeting include:

- inspection of data centres, whether regulated and what standard is used (e.g. ISO 22237); and
- harmonisation of scopes and witnessing of infrequently performed inspections

#### **Laboratory Committee (LC)**

The final meeting of the LC was held in October 2022.

The initiatives around the Digital SI were discussed:

- CIPM-ILAC Joint webinar: Digital Transformation in the context of accreditation 30 June 2022
- NIST Digital SI Conference 28 – 29 September 2022

- 3rd International DCC Conference 28 February to 2 March 2023

There was consensus to reaffirm the current systematic review ballots for ISO/IEC 17011 and ISO/IEC 17034 for another 5 years.

It was agreed that remote assessments lack technical rigor and the LC members advocated returning to on-site assessments as soon as possible:

- remote assessments suffer from communication gaps and challenges in technology (i.e. internet connection)
- in some economies, documents must be physically mailed in, slowing down the process
- costs are often the same for remote and on-site assessment, labs want the value of an on-site assessment
- labs get more benefit from on-site external assessment to demonstrate competency to their upper management

### **Joint IAF CMC & ILAC MCC (Joint Communications & Marketing Working Group)**

NATA's Head of Marketing and Communications, Brendon Moo participates on the ILAC/IAF Communications and Marketing Working Group and chairs the Podcast Working Group.

Regular meetings have been held for the Marketing and Communications professionals to discuss the latest updates. Discussion has included the possible theme for World Accreditation Day 2023 and a shortlist was provided to the ILAC/IAF executive.

The theme selected for **WAD 2023: Accreditation - Supporting the Future of Global Trade**

### **ILAC-WADA Liaison Group**

The ILAC/WADA Liaison Group Terms of Reference have been updated and allow an additional Accreditation Body (AB) representative for ABs with multiple WADA accredited laboratories. NATA now has 2 representatives on the ILAC-WADA Liaison Group - John Styzinski, General Manager Operations and Technical, and Danielle Dicker, Technical Manager.

There are 30 WADA laboratories now accredited, 1 probationary laboratory and 3 candidate laboratories. There are 3 WADA approved laboratories for Athlete Biological Passport (ABP) and 25 ILAC ABs have accredited WADA laboratories (NATA has accredited 5 laboratories).

Several new WADA technical documents (TDs) have been published since the last meeting and these are listed on the WADA website with their effective dates.

### Update - UKAS' toolbox for decision-makers

The aide-memoire (UKAS Decision Toolbox) will not be adopted at this stage but may be revisited in the future if the need arises. It was agreed that use of an aide-memoire document should be during the assessment and not at the accreditation decision stage. It was also discussed that a number of ABs already have in place assessment checklists, including NATA.

### **ILAC Publications**

During the period July-December 2022 a couple of publications were finalised and published.

Revision of a few other documents are still in progress.

Refer spreadsheet 'NATA- Publications'.

## **2. Maintain membership and participate in the Asia Pacific Accreditation Cooperation (APAC)**

### **2.3 Maintain High Level Participation in Relevant APAC Committees**

Meetings scheduled during the July - December 2022 period were conducted virtually as a consequence of the ongoing COVID-19 pandemic. These are summarised on the spreadsheet 'NATA - activities'.

#### **APAC Executive Committee**

APAC sought legal advice from a NZ based law firm regarding compliance with NZ Government sanctions by both APAC itself, member accreditation bodies and their accredited conformity assessment bodies.

It is clear from the legal advice that APAC must comply with NZ law (including sanctions) as APAC is an entity incorporated in NZ. This means APAC cannot provide its services to a sanctioned 'person' (entity or individual) or an associate of a sanctioned person. Therefore, if an APAC member is itself a sanctioned person, or if sanctions are violated by an APAC Member (e.g. member continues to offer accreditation services to a sanctioned person), APAC will be required to take action, including suspension or withdrawal of the APAC membership.

APAC has now advised all its Members to take the necessary action to ensure on-going compliance.

APAC has received information that RusAccreditation (one of the Russian ABs), continues to accredit a business listed as a sanctioned entity. Although the business provides services for its own internal purposes, APAC's legal advice is that the sanctions apply irrespective of an entity's function/purpose and as such, APAC cannot provide services such as international recognition through the APAC MRA. RusAccreditation will therefore be requested to suspend its accreditation of the business or risk suspension from the APAC MRA.

#### **APAC Training Workshops**

##### Accreditation of Testing Laboratories (ISO/IEC 17025)

APAC held a virtual training course on the accreditation of testing laboratories in August 2022 and again in December 2022 which was presented by NATA's Sector Manager Materials, Assets and Products. NATA's Technical Manager was an attendee at the training course in August 2022.

##### Accreditation of Validation and Verification Bodies (ISO/IEC 17029)

APAC held a virtual training course on the accreditation of validation and verification bodies which NATA's Sector Manager Calibration attended.

##### Accreditation of Inspection Bodies (ISO/IEC 17020)

APAC held a virtual training course on the accreditation of inspection bodies which was attended by NATA's Sector Manager Inspection.

##### Accreditation Body Requirements (ISO/IEC 17011)

APAC held a virtual training course on accreditation body requirements which was presented by NATA's General Manager Compliance and Governance. Attendees at the training course included NATA's Technical Manager, NATA's Operations Manager and Assistant Operations Manager, several Sector Managers, and several Accreditation Team Leaders.

##### APAC Food Regulators and Accreditation Webinar

APAC hosted a webinar that was presented by NATA's Sector Manager Life Sciences who is a Co-Convenor of the APAC CPC Food Regulators Working Group on the topic of accreditation for food regulators.

#### **APAC Publications**

During the period July - December 2022 several publications were finalised and published. Refer spreadsheet 'NATA- Publications'.

### **3. Participation in Mutual Recognition Arrangement (MRA) evaluations and related activities**

NATA's Technical Manager, Danielle Dicker participated as a Provisional Evaluator in the evaluation of A2LA, USA in June 2022. Post evaluation work was carried out during the latter half of 2022.

Brett Hyland, NATA's Stakeholder Engagement Manager is participating as an Evaluator in the evaluation of ENAS, United Arab Emirates that is being conducted virtually in January 2023. Preparation for this evaluation commenced in the latter half of 2022.

Refer spreadsheet 'NATA - activities'.



## 4. Represent Australia's interests in relevant international standardisation activities related to conformance

### 4.1 Participate in Relevant ISO Technical Committees

#### ISO/TC 212

NATA's Sector Manager Legal and Clinical Services, Andrew Griffin represents NATA / Standards Australia and ILAC at the ISO TC 212 meeting where progress on the update of ISO 15189 *Medical laboratories - Requirements for quality and competence* and other working group documents are discussed. Andrew Griffin is a member of WG 1 and is the project lead for revision of ISO TS 20658 *Medical laboratories - Requirements for the collection, transport, receipt and handling of samples*.

Project member NWI In-house IVDs and Validation/Verification

#### Plenary

The Plenary provides the opportunity for each Working Group to advise all Plenary members of their activities since the last Plenary, advise of any resolutions as applicable and review current and future work items. WG 2 did not meet and a supplementary report was provided on the recent activities of WG2.

#### ISO/TC 212/WG 1

- ISO 15189 *Medical laboratories - Requirements for quality and competence*  
ISO FDIS 15189 has been approved for publication following closure of ballot.
- ISO 20658 *Medical laboratories — Requirements for collection and transport of samples*.  
ISO DIS 20658 has been approved for publication following closure of ballot
- ISO 22870 *Point-of-care-testing (POCT) – Requirements for quality and competence 2016*  
This standard will be withdrawn as the requirements have been incorporated in the new ISO 15189.
- ISO/PWI 5649 *Medical laboratories - Concepts and specifications for the design, development, production and use of in-house in vitro diagnostic medical devices*  
CD planned for November this year, with a DIS planned for March 2023. This is under review and will depend on the number of comments made. They have until December for the DIS which gives the project more time. There is a conversation on Annexes and how they may be used, no examples have been received by the group. The potential cross over with the validation and verification document was discussed.
- ISO TR23834 *Guidance on application of ISO15189 in anatomic pathology*

Proposals for new projects for WG 1:

- Digital pathology and Algorithm-based Image analysis - A joint project for WGs 1 and 4 with the objective of developing a standardized validation and verification approach for the algorithms.
- ILAC G26 *Guidance for the Implementation of a Medical Accreditation Scheme* - The WG has been asked to set up a task force to consider the future and content of the document with the imminent publication of ISO 15189:2022.
- ISO 17849 PWI *Validation and verification of quantitative and qualitative methods* - Update given on progress of the standard. The group was asked to agree the scope and introduction and the structure of the document was then discussed.

- ISO 22583:2019 *Guidance for supervisors and operators of point-of-care testing (POCT)* devices is due for systematic review in January 2023 and has been sent for ballot. The consensus of WG1 was to confirm this document. However this was not documented as a formal resolution. The recommendation is that it is not ready to be a standard. This should be confirmed as a TS.
- *ISO TS 23824 Guidance on the application of ISO15189 in anatomic pathology* - The review of the document was given to the WG, this was the first draft given the advanced stage of the ISO15189(2022) FDIS. There is no need to adjust the scope but the introduction to expand the use of the document.
- ISO/TS 20914 *Medical laboratories – Practical guide for the estimation of measurement uncertainty* - There is a systematic review planned for Jan 2023. Year 6 is when it needs to be withdrawn, revised, or converted to a standard. WG1 recommendation is for confirmation, there still will be a ballot. There is an error in the document to be fixed regardless of review.

### **ISO TC 281 Fine Bubble Technology (FBT)**

NATA's Sector Manager Life Sciences, Neil Shepherd attended the ISO TC 281 Fine Bubble Technology Plenary and Technical Committee WGs 1-3 as a member of Standards Australia (SA) mirror committee ME 090. FBT has applications in agriculture, environment and industry. Developing technologies based on FBT may increase food production in aqua culture and hydroponics, reducing the need for hazardous cleaning chemicals and aid in soil remediation and water quality improvement.

The WGs are progressing the development and /or revision of several standards on various aspects of FBT, including:

#### WG 1 General principles including terminology

ISO 20480-1, *Fine bubble technology - General principles for usage and measurement of fine bubbles - Part 1: Terminology (revision)*

ISO/CD 20480-5, *Fine bubble technology - General principles for usage and measurement of fine bubbles - Part 5: Shelled fine bubbles*

ISO/PWI TS 20480-6, *Fine bubble technology -- General principles for usage and measurement of fine bubbles -- Part 6: Expression guideline for fine bubble effect on categorized classification by attributes*

ISO/PWI 20480-7 *Fine bubble technology-General principles for usage and measurement – Part 7: Bubble potential energy*

ISO/DTS 24217-1, *Fine bubble technology — Guideline for indicating benefits — Part 1: Classification of effective functions of fine bubbles*

#### WG 2 Fine bubble characterisation and measurement

ISO/AWI 7383 *Fine bubble technology -- Evaluation method for determining oxygen content in fine bubble dispersions in water*

*PWI Fine bubble technology --Characterization of ultrafine bubbles -- Part 1: Data correction to exclude particulate contaminants for evaluating size and concentration indices*

#### WG 3 Applications of fine bubble technology

ISO/AWI TS 21256-4, *Fine bubble technology -- Cleaning applications -- Part 4: Test method for oil removal from polyester based textile*

ISO/PWI 4240-2, *Fine bubble technology -- Environmental applications – Part 2: Test method for evaluating aeration performances.*

ISO/TS 23016-1, *Fine bubble technology — Agricultural applications — Part 1: Test method for evaluating the growth promotion of hydroponically grown lettuce*

ISO/NP 23016-4 *Fine bubble technology – Agricultural applications – Part 4: Test method for evaluating the number concentration of ultrafine bubble (UFB) achieving the promotion of barley seed germination.*

ISO/CD 7428-1, *Fine bubble technology -- Domestic applications -- Part 1: Assessment of showerhead devices by evaluating size and concentration indices of generated fine bubbles*

ISO/CD 7429-1 *Fine bubble technology -- Industrial and consumer device applications -- Part 1: Assessment of nozzles by evaluating size and concentration indices of generated fine bubbles.*

ISO 4240-3 *PWI Fine bubble technology – Environmental applications – Part 3: Test method for on-site algae removal*

ISO 4240-4 *PWI Fine bubble technology – Environmental application – Part 4: Test method for oil removal from soil by washing using fine bubbles*

ISO/PWI TS 11899-1 *Fine bubble technology -- Transportation and dispensing systems for agro- and aqua-cultural applications -- Part 1: Ultrafine bubble concentration loss in ultrafine bubble water passing through long distance plastic pipes*

## **ISO TC 334 Reference Materials**

NATA's Sector Manager Calibration, Paul McMullen participates on ISO TC 334 and its Working Groups that have responsibility for reviewing and re-publishing the guidance documents for reference materials. The following documents are currently being worked by the TC and its WGs.

- ISO Guide 30 (Definitions) to be published as ISO 33400
- ISO Guide 31 (RM documents and certificates) to be published as ISO 33401 and will include Requirements not contained in 17034
- ISO Guide 35 (Characterisation, Stability and Homogeneity of RMs) to be published as ISO 33405 and will include Requirement not contained in 17034. ISO 33405 will only contain requirements for qualitative RMs, see ISO 33406 below
- ISO Guide 8 (Quality Control Materials) may be withdrawn with a Technical Report updated as a replacement
- ISO Guide 33 (Use of Reference Materials) to be published as ISO 33403 and remain guidance only

ISO is also working on a qualitative RM guide along the lines of ISO Guide 35 (ISO 33405) for the characterisation, stability, and homogeneity of Qualitative RMs. This guide will contain requirements not in 17034 and will be designated ISO 33406

## **4.2 Participate in Relevant ISO/CASCO Working Groups**

### **ISO/CASCO Working Group 57 ISO/IEC 17043 revision**

NATA's Sector Manager Calibration, Paul McMullen is a member of the ISO/CASCO Working Group 57 responsible for the revision of ISO/IEC 17043:2010 *Conformity assessment — General requirements for proficiency testing*. ISO/IEC 17043 is used by all Accreditation Bodies for the assessment of competence of providers of proficiency testing schemes.

A drafting group was appointed from the WG57 members to progress the draft ready for publication and Paul McMullen was appointed to the drafting group.

It is expected that the revised standard will be published mid-2023.

### **4.3 Participate in Relevant Codex Alimentarius Committee on Methods of Analysis and Sampling (CCMAS)**

#### **AOAC Annual Meeting and Exposition**

NATA's Sector Manager Life Sciences, Neil Shepherd attended the AOAC annual meeting and exposition held in the USA in September 2022. This meeting attracted a global audience of participants and technical developments in food testing including allergens, gluten testing and cannabis testing were discussed.

#### Analytical Solutions Forum

The Analytical Solutions Forum held included speakers from the World Health Organisation (WHO), US Food Safety Inspection Scheme (FSIS), Centers for Disease Control and Prevention (CDC), Dept Good Agricultural Practice Mexico and DAFF

The WHO want to improve harmonisation of methods, including sampling methods; taking representative samples and development of harmonised sampling methods is needed to improve consistency of data. WHO also mentioned the ongoing need to strengthen technical capacity in developing economies.

Sodium, sugar and trans-fats have been targeted as major contributors to poor health. Consequently, WHO are developing biomarker analysis to study the nutrition status of economies, sub populations and individuals.

The US FSIS raised the challenge associated with the amount of data generated by high throughput sequencing that then requires analysis and storage. They also stated that they would like to see more focus on salmonella as this pathogen has not declined to the same amount as other food borne pathogens.

The CDC further noted that there have only been minor improvements in the incidence of food borne diseases since HACCP was introduced. Their goal is to reduce foodborne disease by 20-40% per microorganism by 2030.

#### AOAC Food Authenticity WG

The AOAC Food Authenticity WG has developed 13 Standards Method Performance Criteria (SMPR) for food authenticity, and others are under development including saffron, turmeric powder and vanilla extract. The challenges are to define authenticity, undertake validations and identify natural variation in authentic products.

#### Reference materials

Homogeneity and stability remain the biggest issues for microbiological reference materials. Reference materials for cyanotoxins have been developed and certified reference materials should be available before the end of 2022.

Certified reference materials are also now available for a range of pesticides in cannabis.

#### Cannabis Analytical Science Program (CASP)

An update was provided on the work of the CASP WGs, including:

- launching of Standards Method Performance Criteria for microorganisms in edibles.
- Certification for Cannabis Chemists by the National Registry of Certified Chemists.
- use of AOAC methods required by the Agriculture Improvement Act 2018 and recommendation for accreditation to ISO/IEC 17025.
- LCMSMS multiplex method developed to detect 102 pesticides and 5 mycotoxins.

Improvement in methods for Legionella and other water borne pathogens.

Industry wants to move to rapid methods, such as qPCR, for legionella detection instead of the plate method that takes 7-10 days to give a result. It is likely to cause acceptance issues with regulators as the reporting units are different for qPCR and plate count.

Demand for Vibrio testing is on the increase due to a rise in the global sea temperature. A multiplex PCR method has been developed for detection of V cholera, V parahaemolyticus and V vulnificus. It may face similar acceptance issues from regulators where plate method is currently required.

Artificial intelligence (AI) and machine learning to detect food fraud.

Development work is in progress to use AI and machine learning to detect food fraud; a proof of concept has been successful.

## **5. Represent Australia's interests in the OECD Working Group on Good Laboratory Practice as the national compliance monitoring authority**

### **OECD Working Party on GLP**

NATA's GLP Program Advisor, Louise Calder is the Chair of the OECD Working Party on GLP, and activities carried out during this reporting period included addressing actions from the 35th Working Party meeting and preparing for the 36th Working Party meeting scheduled for April 2023.

Louise Calder, along with a NATA Lead Accreditation Specialist, also attended the 15th OECD GLP Inspectors' Training Course held in Montreal in October 2022 that was hosted by the Standards Council of Canada. The training course is a biannual event to ensure GLP inspectors learn about the latest innovations, best practices, and encourage harmonisation across monitoring authorities. It comprises lectures and discussions focusing on strategies and practical aspects of GLP inspections as well as parallel workshops. The inspection of Information Technology Systems and the newly declassified OECD GLP Document on Data Integrity was highlighted. She also attended an IT webinar on this topic.

Louise Calder is a member of the Steering Committee responsible for the training course and presented a lecture on Test item and ran an associated role play.

In November 2022, Louise Calder was the Lead Evaluator for the on-site evaluation of the GLP compliance monitoring program administered by the Argentinian Organisation for Accreditation (OAA) in Buenos Aires. The visit was conducted over 4 days and included a review of the Argentina GLP program as well as observing the conduct of a GLP inspection by OAA staff.

## **6. Provide Technical Support for Government Free Trade Agreements & Mutual Recognition Arrangements; Liaise with Foreign Accreditation Bodies focussing on economies of Australia's major or emerging trade partners; Lead & Participate in Regional Technical fora & capacity building activities**

NATA continues to engage with the DISR Trade Facilitation Section on a range of topics of mutual interest and during this period engagement has primarily been of a routine nature around ongoing programs and activities.

### **6.1 Provide technical support for Government FTAs and Mutual Recognition Arrangements**

NATA responded to requests from the DISR Trade and International Branch and provided inputs/comments on a range of matters, including:

- WTO Conformity Assessment Procedures Guidelines
- queries in relation to FTAs
- export trade issues
- Performance review of the Memorandum of Understanding between the Commonwealth and NATA.
- Australia's new formalized process for applications to the APEC Support Program: Design Framework and Project Proposal.
- Participated in discussions and provided feedback on a concept note for a Standards and Conformance Trade Enabling Program with India to bring together Indian and Australian standards and conformance bodies and reduce technical barriers to trade (TBT), build sustainable partnerships and identify business opportunities where standards, conformity assessment and metrology processes are aligned.
- Discussion with other TIA members and the PACER Plus Implementation Unit (PPIU) advisors to gain an understanding of existing activities in the Pacific (to avoid duplication) and ascertain potential opportunities under PACER Plus for future programs.

### **6.3 Cooperation between NATA and IANZ**

The NATA Chair, David Turner and CEO, Jennifer Evans attended the meetings of the IANZ Accreditation Advisory Committee and Council (Board of Directors) on 29 and 30 August 2022 respectively. This was the first occasion attendance in person has been possible since the meetings in 2018. Although there were no specific outcomes, it is a resumption of reciprocal attendance at meetings of Boards of Directors by the respective Chairs and CEOs. An invitation has been accepted by the IANZ Chair, Paul Connell and CEO, Brian Young to attend the NATA Board meeting in March 2023.

Several of NATA's Sector Managers/ Deputy Sector Managers participated in the annual meetings of the IANZ Professional Advisory Committees (PAC) meetings scheduled during this reporting period.

NATA and IANZ technical management attend each other's respective technical advisory committee meetings due to the close relationship between Australia and New Zealand. It provides an opportunity to:

- Improve understanding of IANZ implementation of accreditation standards in similar testing facilities and inspection bodies to those within NATA;
- To answer questions arising about how NATA approaches common problems.
- To provide NZ PAC members and IANZ information on current issues encountered by NATA

The CEO's report was presented at each of the PAC meetings by the CEO Brian Young or a delegate, and covered:

- Change of management at IANZ; Brian Young appointed CEO in July 2021

- The impact of COVID restrictions to IANZ operations
- IANZ has updated its procedures for how assessments can be conducted, and onsite assessments are not the only option; desktop, remote, and a hybrid of onsite and remote activities are available.
- IANZ - Strategic plan - Statement of Intent (SOI) 2022 - 2026

The SOI is operationalised in a Statement of Performance Expectations (SPE), which outlines the deliverables for the forthcoming financial year, along with measures and targets. The SOI and SPE are approved by the Minister of Commerce and Consumer Affairs.

- IANZ's next MRA Evaluation is in March 2023.

#### Metrology and Calibration PAC (MCPAC)

NATA's Sector Manager Calibration attended the MCPAC meeting where the newly appointed Chief Metrologist of New Zealand, Annette Koo, presented a report detailing significant changes in New Zealand's technical infrastructure, including the merging of 3 PACs, proficiency testing schemes and research on Quantum Random Generators a new area of Quantum Metrology.

The Program Manager provided an update on new accreditations, assessment staff (internal and external), PT activities undertaken by the calibration laboratories and programme statistics (number of accreditations). It was also noted that the IECEE CB scheme and OSHA have implemented a new requirement that all in-house calibrations must now be covered by a separate Calibration Accreditation.

NATA presented a report on our Calibration sector which generated good technical discussions. Topics covered included:

- Transformer verification through secondary injection modelling technique.
- Reporting due dates on calibration certificates.
- Reporting measurement uncertainties much less than an instruments resolution.
- The SI Digital Framework and machine-readable calibration certificates, noting the new technical infrastructure being developed by the BIPM.

#### Biological and Chemical PAC

This meeting was held face-to-face and attended by the Deputy Sector Manager Life Sciences.

The Program Manager provided an update on a Memorandum of Understanding with Taumata Arowai (Water Services Regulator) appointing IANZ as the laboratory accreditation body under the Water Services Act 2021, changes to the drinking water standards, the Recognised Laboratory Programme activities, and growth in the Chemical program.

#### Inspection PAC

An update was provided on activities in the inspection sector by PAC members, including interest for inspection accreditation in new areas such hydrogen gas, hydrogen liquid (cryogenic) and ammonia piping and the need for guidance materials in these areas. There have also been enquiries from the space agency and border security.

A need for more technical experts has been identified and the topic was raised as to whether or not remote use of technical assessors from other countries e.g. US, Canada etc. could be considered.

There was also discussion about the review of ISO/IEC 17020, use of available technologies for remote assessments to reduce accreditation costs for facilities to make visits more effective and a risk-based approach to perhaps reducing assessment intervals. No decisions were made.

#### Medical Testing PAC

Pathology in NZ has a new oversight body which is part of the Ministry of Health; it is thought it will move pathology to central oversight but there have been no changes to date.



In NZ there is no body for the oversight of Medical Devices, unlike Australia with the TGA, but Covid has highlighted the need for regulations around the import of tests with the market having been flooded. Anecdotally, up to 50% of the tests did not meet requirements.

There was extensive discussion on Clinical supervision, the role of the pathologist and the clinical scientist. Representatives were aware of the requirements of the NPAAC supervision documents and that ultimate responsibility for testing is with the pathologist, however, there is not the work force in NZ to meet the NPAAC requirements. There was real concern about how this should be addressed and a risk assessment for the government was suggested as a way forward.

IT systems were identified as a major source of risks for laboratories and IANZ will be looking very closely at the implementation of the new NPAAC IT document.

There was interest in several topics detailed in the report from NATA including:

- the disjointed nature of molecular testing and the impact of overseas labs moving into the market (there is little molecular testing currently in NZ)
- multisite accreditation model introduced by NATA and how this is managed. Several members present thought this had real economies
- Biobanking –IANZ has had some interest in accreditation but at this stage are not offering a program and are interested in NATA's experience to date.

#### Physical Sciences PAC

IANZ and NATA have the same concerns regarding the NDT Standards Committee. No-one understands why Standards Australia insists on the withdrawal of the Australian Standards and replacing them with ISO. It was noted again that the ISO standards are not equivalent in many aspects, and that the failure to replace one of the withdrawn AS is causing as much disruption in NZ as it is here.

Some concern was expressed regarding requests for extensions to scope for specifications and technical guides that are not methods. NATAs position was discussed – any specs should only be in the limitations, not the Procedures.

There was a general discussion about how to reduce accreditation costs for facilities. Travel is not a major factor since nothing is far away (comparatively). However, they did talk about how to make visits more effective; most Committee members seemed to be thinking about reducing QMS reviews, more remotes when technically viable, and a risk-based approach to perhaps reducing assessment intervals.

### **6.5 Promote development and assist with capacity building for countries in the region**

#### Pacific Island Forum (PIF) activities

NATA's General Manager Stakeholder Relations has maintained regular contact with Dr Ulrich Diekmann, Regional Quality Infrastructure Coordinator Pacific Islands Forum Secretariat and participated in meetings to discuss how NATA could assist laboratories in the Pacific Island region with understanding testing and accreditation requirements.

PIFS conducted a Needs Assessment on Testing survey of laboratories and came up with an action list of priorities for the next 12 months. It was determined that there was a need for training for laboratories and NATA provided a proposal to provide training on quality management and ISO/IEC 17025 in 2023.

## **7. Other activities with public interest outcome (as agreed)**

### **7.1 Management of Deeds of Agreement**

Information on MOUs and Deeds of Agreement, including those current, under negotiation or renegotiation is provided in the spreadsheet 'NATA- MOUs'. The following agreements are noted:

#### Commonwealth

##### Services Australia and Department of Health

The governance and working group meetings have continued under the tripartite Deed of Agreement between NATA, the Department of Health and Services Australia. There are 4 working group meetings and 2 governance meetings per year. The Deed places considerably more reporting responsibilities on NATA including the preparation of quarterly reports on activities undertaken during the period.

Quarterly informal meetings are held with Services Australia to address operational issues that arise.

##### Department of Agriculture, Fisheries and Forestry (DAFF)

In support of areas covered by the Deed of Agreement and Memorandum of Understanding, NATA's Sector Manager Life Sciences attended the 3rd Australian Authorised Officers (AAO) Annual Meeting and provided an update on NATA's accreditation activities covered by the Deed, including changes to the meat inspection program. Attendees included all organisations that provide Authorised Officers.

The Sector Manager Life Sciences also attended a meeting hosted by DAFF of NATA accredited facilities approved by DAFF to test imported food samples. Information was provided by DAFF on changes to the surveillance and risk foods program and feedback sought.

##### National Blood Authority

NATA has signed a MOU with the NBA in relation to laboratories performing tests on blood and blood products.

#### State and Territory

##### State Health Department MOUs

The MOU with Northern Territory is currently under review as it is due for renewal.

##### Victorian Asbestos Eradication Agency (VAEA)

The VAEA approached NATA regarding issues with asbestos testing and expressed interest in formalising the relationship with NATA and working more closely on asbestos matters. A MOU was signed in December 2022 covering both testing and inspection accreditation.

### **7.2 Representation on Standards Australia Committees**

Refer spreadsheet 'NATA- Committee Positions'.

#### **Other activities**

##### National Measurement Institute

NATA's Sector Manager Calibration, Paul McMullen met with NMI's Legal Metrology personnel to discuss conformity assessment of electric vehicle charging stations.

##### Australian Building Codes Board (ABCB) WaterMark Technical Advisory Committee (WMTAC)

NATA's Sector Manager MAP participates on WMTAC; and reviews, provides feedback, and addresses queries on a range of standards and specifications (refer below) for plumbing and

drainage products for compliance with the WaterMark Certification Scheme in accordance with the Plumbing Code of Australia (Volume 3 of the National Construction Code).

The WaterMark Certification Scheme is a mandatory certification scheme for certain plumbing and drainage products to ensure that plumbing and drainage products are fit for purpose and appropriately authorised for use in plumbing or drainage installations. Whilst some products are manufactured in Australia, many these products are imported.

To achieve WaterMark certification, a product must:

1. be tested by an accredited testing laboratory;
2. comply with an applicable specification;
3. be manufactured in accordance with an approved quality management system; and
4. clearly state its intended scope of use.

WaterMark Technical Specifications (WMTS) are published by the Australian Building Codes Board (ABCB), as part of their role in managing and administering the scheme. Other product specifications or standards are developed and published by third parties, including but not limited to Australian (AS) or Australian/New Zealand (AS/NZS) standards, European Standards (EN), International Electrotechnical Commission (IEC) Standards and International Organisation for Standardisation (ISO) Standards. A WMTS or third party published specification may be developed, where no approved specification can be used for evaluating a plumbing or drainage product.

#### Australian Building Codes Board (ABCB) Lead Free Certification Procedures Working Group

NATA's Sector Manager, Materials, Assets and Products Diane Hobday participates on this working group.

This group (consisting of representatives of three WaterMark Conformity Assessment Bodies, NATA, JAS-ANZ and ABCB) has been established to consider critical aspects of product certification including evaluation, materials and testing in relation to ABCB's initiative to implement lead free requirements for any plumbing product containing copper alloy and intended for use in contact with drinking water. Whilst some plumbing products are manufactured in Australia, many of these products are imported.

#### Centre for Pavement Engineering Education (CPEE) Training

Diane Hobday NATA's Sector Manager, Materials, Assets and Products is the presenter for the training of post-graduate engineers to educate them regarding the content and concerns arising from NATA reports in the GCCMT industry. Training is performed in the national interest to develop competency of early-career engineers.

#### Commonwealth Department of Health and Aged Care Haemopoietic Progenitor Cell (HPC) Sector Clinical Advisory Group

Wendy Harris, a Lead Accreditation Specialist for Human Pathology represents NATA on this clinical advisory group that provides advice to support the implementation of the National Haemopoietic Progenitor Cell Framework. The framework will ensure future arrangements continue to improve access to HPC transplants for Australians.

#### Australian Institute for Non-Destructive Testing (AINDT) NDE 4.0 Committee

Nick Di Cresce, Deputy Sector Manager Materials, Assets and Products attends the management committee meetings held every 2 months that discusses national and global aspects of NDE 4.0. The impact of new technologies on the NDT industry are discussed, including Artificial Intelligence, Internet of Things (IoT) and machine learning.